TAMPEREEN TEKNILLINEN YLIOPISTO
TAMPERE UNIVERSITY OF TECHNOLOGY

OUTI SOIKKELI

UPDATING AND IMPLEMENTING QUALITY MANAGEMENT SYSTEMS ACCORDING TO ISO 9001:2015 AND IATF 16949:2016 STANDARDS

Master of Science Thesis

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ABSTRACT

OUTI SOIKKELI: Updating and Implementing Quality Management Systems according to ISO 9001:2015 and IATF 16949:2016 Standards
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Quality can be defined as fitness for use or conformance to requirements. Organizations can create and utilize a Quality Management System (QMS) for managing its operations. International Organization for Standardization (ISO) publishes standards, such as ISO 9001:2015. International Automotive Task Force (IATF) has published IATF 16949:2016 standard for the supply chain of automotive industry. IATF 16949:2016 is a standard based on ISO 9001 but it offers supplemental requirements. IATF 16949:2016 focuses on continuous improvement, defect prevention, reducing variation and waste in supply chain. An organization needs to have ISO 9001 certification before it can be certified according to standard IATF 16949:2016.

This research was done at Ahlstrom-Munksjö, Tampere Mill (AMTM). Tampere Mill has a valid ISO 9001 certificate from the previous version 2008. The objective of the study was to find out gaps in the organization's QMS in order to meet ISO 9001:2015 and IATF 16949:2016 requirements. Another objective was to analyze the gaps and implement actions towards conformity. The research methodologies were literature review, interviews and observations. A literature review was conducted on quality management standards ISO 9001:2015 and IATF 16949:2016, in addition a research on academic researches was conducted. The interviews and observations of daily activities were also research methods determining the level of conformance.

By request of the organization where this study was done, the results are not published in this public version. As the next step, the organization develops a carefully created implementation plan that fits the best for the needs and timelines of AMTM. However, meeting the requirements can take time. Alignment and commitment in the enhancement of each operating function are essential in the organization.

Once the implementation plan has been designed, a practical step is to update the existing system. Evidence of conformity is gained by executing internal audits on the QMS as a whole, as well as perform process and product audits. Ultimately the audit results, through proper corrective actions, will offer evidence of conformance to both ISO 9001:2015 and IATF 16949:2016 standards to aim for certification.

TIIVISTELMÄ

OUTI SOIKKELI: Updating and Implementing Quality Management Systems according to ISO 9001:2015 and IATF 16949:2016 Standards
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Laatu voidaan määritellä sopivuutena tarkoitukseensa tai vaatimusten täyttymisenä. Organisaatiot voivat hyödyntää laadunhallintajärjestelmää johtaakseen toimintaansa. International Organization for Standardization (ISO) julkaisee standardeja, kuten ISO 9001:2015. International Automotive Task Forcen (IATF) julkaisema IATF 16949:2016 on standardi autoteollisuuden toimitusketjulle. IATF 16949:2016 perustuu ISO 9001:seen, mutta se asettaa lisävaatimuksia. IATF 16949:2016 painottaa jatkuvaa parantamista, virheiden ehkäisyä, ja vaihtelun sekä hukan vähentämistä toimitusketjussa. Organisaation tulee sertifioida ISO 9001 ennen kuin se voidaan sertifioida standardin IATF 16949:2016 mukaan.

Tämä tutkimus tehtiin Ahlstrom-Munksjön Tampereen tehtaalle (AMTM). Tampereen tehtaalla on voimassa oleva ISO 9001 sertifiointi edellisestä, vuoden 2008 versiosta. Työn tavoitteena oli löytää organisaation laadunhallintajärjestelmästä kohdat, jotka puuttuvat ISO 9001:2015 ja IATF 16949:2016 vaatimuksista. Toinen tavoite oli analysoida puutteet ja jalkauttaa toimenpiteitä, joilla päästään kohti vaatimustenmukaisuutta. Käytetyt tutkimusmenetelmät olivat kirjallisuuskatsaus, haastattelut ja havainnointi. Kirjallisuuskatsauksessa tutustuttiin laadunhallintastandardeihin ISO 9001:2015 ja IATF 16949:2016, sekä lisäksi akateemisiin tutkimuksiin. Haastattelut ja havainnointi päivittäisestä toiminnasta toimivat myös metodeina vaatimustenmukaisuuden tilan määrittämiseksi.

Yrityksen pyynnöstä tutkimuksen tuloksia ei julkaista tässä julkisessa versiossa. Analyysin jälkeen seuraava askel on laatia harkiten jalkauttamissuunnitelma, joka parhaiten sopii AMTM:n tarpeisiin ja aikatauluun. Vaatimusten täyttyminen voi kuitenkin viedä aikaa. Organisaation toimintojen linjaus ja sitoutuminen parantamiseen ovat olleellisisa asioita.

Kun jalkauttamissuunnitelma on suunniteltu, sen perusteella käytännön askel on päivittää olemassa oleva laadunhallintajärjestelmä. Todisteet vaatimustenmukaisuudesta saadaan suorittamalla sisäisiä auditointeja laadunhallintajärjestelmään kokonaisuudessaan, ja auditoida prosesseja sekä tuotteita. Lopulta auditointitulosten perusteella, ja asianmukaisten korjaavien toimenpiteiden perusteella, voidaan saavuttaa standardien ISO 9001:2015 ja IATF 16949:2016 vaatimustenmukaisuus sertifioinnin saavuttamiseksi.

PREFACE

A few years ago I was wondering how it feels to write the preface to my Master's Thesis. Now is the moment and the sentences are written with a combination of happiness, relief and longing. It feels challenging to collect all the experienced moments into a couple of sentences. The studies at TUT were interesting and adequately challenging, but the time to work on this Thesis was even more rewarding. I am happy to get the chance to increase my knowledge in the field of quality.

I would like to thank the personnel of Ahlstrom-Munksjö, Tampere Mill for the co-operation during the time that I was working on this Thesis. Especially I appreciate and thank for the support and encouragement of the Plant Manager, Nicolas Evrard. In addition, I want to thank Jurkka Kuusipalo and Ulla Saari for valuable comments from the side of Tampere University of Technology.

The studies and this Thesis has taken multiple hours during weekday evenings and weekends, therefore, I want to thank grandparents for taking care of our kids in the meantime. Lastly, I wish to address my greatest thanks to my family, Mikko and our two lovely daughters, for strengthening the believe in my work during the studies: Thank you.

Tampere, 22 May 2017

Outi Soikkeli

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ABBREVIATIONS, TERMS AND SYMBOLS

AIAG	Automotive Industry Action Group, USA
AMTM	Ahlstrom-Munksjö, Tampere Mill
ANFIA	Associazione Nazionale Filiera Industrie Automobilistiche, Italy
APQP	Advanced Product Quality Planning
CL	Centerline
CSR	Customer Specific Requirements
DFSS	Design for Six Sigma
DMAIC	Define, Measure, Analyze, Improve, Control
FIEV	Fédération des Industries des Équipements pour Véhicules, France
FMEA	Failure Mode and Effect Analysis
HR	Human Resources
IATF	International Automotive Task Force
ISO	International Organization for Standardization
KM	Knowledge Management
KPI	Key Performance Indicator
LCL	Lower Control Limit
MSA	Measurement System Analysis
OEM	Original Equipment Manufacturer
PDCA	Plan-Do-Check-Act cycle
PPAP	Product Part Approval Process
QFD	Quality Function Deployment
QM	Quality Management
QMP	Quality Management Principle
QMS	Quality Management System
SFS	Finnish Standards Association
SMMT	Society of Motor Manufacturers and Traders Ltd., UK
SPC	Statistical Process Control
SWOT	Strengths, Weaknesses, Opportunities, Threats
TQ	Total Quality
TQM	Total Quality Management
TUT	Tampere University of Technology
UCL	Upper Control Limit
VDA	Verband der Automobilindustrie e.V., Germany

APQP	"Product quality planning process that supports development of a product or service that will satisfy customer requirements, APQP serves as a guide in the development process and also a standard way to share results between organizations and their customers" (IATF 16949:2016)
Audit	"Systematic, independent and documented *process* for obtaining *objective evidence* and evaluating it objectively to determine the extent to which the *audit criteria* are fulfilled." (SFS-EN ISO 9000:2015, SFS-EN ISO 19011:2011)

	"The on-site *verification* activity, such as inspection or examination, of a *process* or quality system, to ensure compliance to *requirements*. An *audit* can apply to entire *organization* or might be specific to a function, *process* or production step." (Nelsen & Daniels 2007)
Audit criteria	"Set of *policies, procedures* or *requirements* used as a reference against which *objective evidence* is compared." (SFS-EN ISO 9000:2015, SFS-EN ISO 19011:2011)
Benchmarking	"An *improvement process* in which an *organization* measures its strategic operations or internal *process performance* against that of best-in-class *organizations* within or outside its industry." (Sower 2011)
Capability	"The total range of inherent *variation* in a stable *process* determined by using data from *control charts*." (Nelsen & Daniels 2007)
Conformance	"An affirmative indication or judgement that a product or service has met the *requirements* of a relevant specification, contract or regulation." (Nelsen & Daniels 2007)
Control chart	"A chart with upper and lower *control limits* on which values of some *statistical* measure for a series of samples or subgroups are plotted. The chart frequently shows a central line to help detect a trend of plotted values toward either *control limit*." (Nelsen & Daniels 2007)
Control limits	"The natural boundaries of a *process* within specified confidence levels, expressed as the upper control limit (UCL) and the lower control limit (LCL)." (Nelsen & Daniels 2007)
Control plan	"*Documented* description of the systems and processes required for controlling the manufacturing of product." (IATF 16949:2016)
Data	"Facts about an *object*." (SFS-EN ISO 9000:2015)
Defect	"*Nonconformity* related to an intended or specified use." (SFS-EN ISO 9000:2015)
Document	"*Information* and the medium on which it is contained." (SFS-EN ISO 9000:2015)
Effectiveness	"The state of having produced a decided on or desired effect." (Nelsen & Daniels 2007)
Efficiency	"The ratio of the *output* to the total *input* in a *process*." (Nelsen & Daniels 2007)

External customer	"A person or *organization* that receives a product, service or *information* but is not part of the *organization* supplying it. Also see 'internal customer'." (Nelsen & Daniels 2007)
Failure	"The inability of an item, product or service to perform *required* functions on demand due to one or more defects." (Nelsen & Daniels 2007)
FMEA	"A systematic group of activities to recognize and evaluate the potential *failure* of a product or *process* and its effects, identify actions that could eliminate or reduce the occurrence of the potential *failure* and *document* the *process*." (Nelsen & Daniels 2007)
Improvement	"Activity to enhance *performance*." (SFS-EN ISO 9000:2015)
Information	"Meaningful *data*." (SFS-EN ISO 9000:2015)
Inputs	"The products, services and material obtained from suppliers to produce the *outputs* delivered to *customers*." (Nelsen & Daniels 2007)
Internal customer	"The recipient (person or department) within an *organization* of another person's or department's *output* (product, service or *information*). Also see 'external customer'." (Nelsen & Daniels 2007)
Management	"Coordinated activities to direct and control an *organization*" (ISO 9000:2015)
Measure	"The criteria, metric or means to which comparison is made with *output*." (Nelsen & Daniels 2007)
Nonconformity	"Non-fulfillment of a *requirement*." (SFS-EN ISO 9000:2015)
Object	"Entity, item, anything perceivable or conceivable." (SFS-EN ISO 9000:2015)
Objective evidence	"*Data* supporting the existence or *verify* of something." (SFS-EN ISO 9000:2015)
OEM	"A company that uses product components from one or more other companies to build a product that it sells under its own company name and brand. Sometimes mistakenly used to refer to the company that supplies the components." (Nelsen & Daniels 2007)
Organization	"Person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its *objectives*." (SFS-EN ISO 9000:2015)
Outputs	"Products, materials, services or *information* provided to customers (internal or external), from a *process*." (Nelsen & Daniels 2007)

PDCA	"A four-step *process* for quality *improvement*. In the first step (plan), a way to effect *improvement* is developed. In the second step (do), the plan is carried out, preferably on a small scale. In the third step (check), the effects of the plan are observed. In the last step (act), the results are studied to determine what was learned and what can be predicted. The plan-do-check-act cycle is sometimes referred to as the Shewhart cycle. (Nelsen & Daniels 2007)
Performance	"*Measurable* result." (SFS-EN ISO 9000:2015)
Policy	"Intentions and direction of an *organization* as formally expressed by its *top management*." (SFS-EN ISO 9000:2015)
Procedure	"Specified way to carry out an activity or a *process*." (SFS-EN ISO 9000:2015)
Process	"Set of interrelated or interacting activities that use *inputs* to deliver an intended result." (SFS-EN ISO 9000:2015)
QMS	"A formalized system that *documents* the structure, responsibilities and *procedures* required to achieve *effective* quality management." (Nelsen & Daniels 2007)
Quality	"A subjective term for which each person or sector has its own definition. In technical usage, quality can have two meanings: 1. the characteristics of a product or service that bear on its ability to satisfy stated or implied needs; 2. a product or service free of deficiencies. According to Joseph Juran, quality means 'fitness for use'; according to Philip Crosby, it means '*conformance* to *requirements*'." (Nelsen & Daniels 2007)
R-chart	"Range chart, A *control chart* in which the subgroup range, R, evaluates the stability of the *variability* within a *process*." (Nelsen & Daniels 2007)
Reliability	"The probability of a product's performing its intended function under stated conditions without *failure* for a given period of time." (Nelsen & Daniels 2007)
Requirement	"Need or expectation that is stated, generally implied or obligatory." (SFS-EN ISO 9000:2015)
Risk	"Effect of uncertainty on objectives." (SFS-ISO 31000:2009)
Risk management	"Coordinated activities to direct and control an *organization* with regard to *risk*." (SFS-ISO 31000:2009)
Specification	"A *document* that states the *requirements* to which a given product or service must *conform*." (Nelsen & Daniels 2007)

Stakeholder	"Any individual, group or *organization* that will have a significant impact on or will be significantly impacted by the *quality* of a specific product or service." (Nelsen & Daniels 2007)
Standard	"A *document* that provides *requirements*, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, *processes* and services are fit for their purposes." (Wilson & Campbell 2016)
Statistics	"A field that involves tabulating, depicting and describing *data* sets; a formalized body of techniques characteristically involving attempts to infer the properties of a large collection of *data* from inspection of a sample of the collection." (Nelsen & Daniels 2007)
Top management	"Person or group of people who directs and controls an *organization* at the highest level." (SFS-EN ISO 9000:2015)
Validation	"Confirmation, through the provision of *objective evidence*, that the *requirements* for a specific intended use or application have been fulfilled." (SFS-EN ISO 9000:2015)
Validity	"The degree to which the method used to collect the *data* actually measures what it is intended to *measure*." (Sower 2011)
Variation	"A change in *data*, characteristic or function caused by one of four factors: special causes, common causes, tampering or structural variation." (Nelsen & Daniels 2007)
Verification	"Confirmation, through the provision of *objective evidence*, that specified *requirements* have been fulfilled." (SFS-EN ISO 9000:2015)
X-chart	"Average chart." (Nelsen & Daniels 2007)

i	individual sample
k	number of samples (subgroup)
n	sample size
$\bar{x}$	mean value
$\bar{\bar{x}}$	overall mean value
R	range
$\bar{R}$	mean range

1. INTRODUCTION

1.1 General

Quality Management Systems (QMS) can be created and utilized in organizations. The purpose of a QMS is to fulfill customer needs, quality requirements and quality expectations. Customer needs are identified through designing, developing, producing, delivering and supporting products or services. (Summers 2005) An effective QMS creates financial benefits, eases both internal and external actions on an organization and increases customer satisfaction (Yasenchak 2016).

International Organization for Standardization (ISO) is a committee providing standards. ISO 9001 is a standard for organizations to demonstrate that it is able to provide products and services meeting customer demands. A second objective of ISO 9001 is to improve customer satisfaction level. (ISO 9001:2015) Another body publishing standards is *International Automotive Task Force* (IATF) which operates in automotive industry. IATF 16949 is a standard which is based on ISO 9001:2015, but offers supplemental requirements to it. IATF 16949 has a strong customer-orientation including several *Customer Specific Requirements* (CSR) and introducing more demanding requirements for automotive production and relevant service parts organizations. (IATF 16949:2016)

1.2 Research Objective and Scope

The research was done at Ahlstrom-Munksjö, Tampere Mill (AMTM). The organization operates in filtration and performance business area and it is one of the leading filter media suppliers worldwide. The organization produces filter media as roll goods dedicated to Liquid and Air Filtration through wet laid technology. The research was conducted in AMTM and its processes. The timescale for the Master's Thesis was 6 months.

The objective of this research was to find and analyze the gaps in order to meet ISO 9001:2015 requirements in the QMS of AMTM. The organization holds a valid certification for ISO 9001:2008. However, new the version of ISO 9001 has been published in 2015 and the transition period of the new standard ends in the autumn of 2018 (ISO 2017).

A second part of the research was to find and analyze the gaps to meet IATF 16949:2016 requirements. The goal of IATF 16949:2016 is to develop organization's QMS to provide continuous improvement, emphasize defect prevention and reduce variation and waste in the supply chain (IATF 16949:2016). AMTM has adapted some of the requirements, but there are still gaps in case the organization wants to aim at the certification of IATF 16949 in the future. At the moment, there is no IATF 16949 certificate in AMTM. Based on the gap analysis, a practical research part was to implement actions towards conformity to meet both ISO 9001:2015 and IATF 16949:2016 requirements. Actions to fulfill requirements were planned to emphasize process approach.

1.3 Research Methodology

There is always a personal motivator fact that inspires to perform a scientific research. The motivator can be the will to know more or to know the truth. Tangible or instrumental goals might be in interest from the financing bodies. (Järvinen 2012) This research was done for the interest to learn about QMS and the writer had a chance to increase personal knowledge in this wide field of QMS. The research had mutual benefits, though. AMTM, where this research was done, had a need to find the gaps to meet the requirements in ISO 9001:2015 and IATF 16949. In addition, the research provides explanations what requirements mean in practice in AMTM along with offering tools to comply with selected requirements.

The objective of the research, as presented, was to find the existing gaps to meet the new ISO 9001:2015 and IATF 16949:2016 requirements. To find the gaps, an analysis was done to the QMS of AMTM including review in related documents in the QMS, executing interviews and observing the overall system functionality in practice. The methodologies used in this research were literature review (books, academic research, articles), interviews (structured, open, discussion) and observations on the daily activities in AMTM. Each of the methods is presented below in more detail.

"No matter which conclusion is reached, the results are judged as a contribution to knowledge" (Järvinen 2012). A research always increases the level of knowledge and the emphasis is in increasing knowledge of all stakeholders. The importance is to gain the level of knowledge slowly and afterwards it is able to have more effective results as the objective is the same. "You must, however, relate your research problem to your resources" (Järvinen 2012). The concept of QMS is broad. Boundaries had to be set at the beginning of the project to succeed in the set timeframe. The information was gathered in the best possible way in respect of the starting point of the researcher.

1.3.1 Literature Review

"In order to know whether the gap or the conflict exists, a researcher must find the recent literature review" (Järvinen 2012). In this research, the literature review started with studying SFS-EN ISO 9001:2015 and IATF 16949:2016. Other related standards, for example SFS-EN ISO 9000:2015, SFS-EN ISO 9004:2009 and SFS-EN ISO 19011:2011 were also studied. Another source for the review was to collect quality literature, revealing the basic, theoretic information on quality. In addition, review on quality and QMS related scientific articles gave a valuable touch on how both quality as a concept and QMS's are to apply in practice. Another interesting point of view was to study what kind of possible drawbacks and limitations appear in organizations that utilize QMS's.

The above mentioned ISO standards were available in the *Tampere University of Technology* (TUT) in SFS Online (TUT 2017). IATF 16949:2016 was purchased by AMTM from *Automotive Industry Action Group* (AIAG). Understanding these standard requirements was also the ground before conducting the actual gap analysis. Support for understanding the standard requirements was gathered through reviewing the latest academic researches and articles as the next step.

For this Thesis the basic information on quality and the definitions were found in the books of the quality branch, however, a broader understanding about possible problems, challenges and practical experience were constructed through academic research review. TUT provided a path to academic research world by the Andor and Science Port systems using keywords, such as "ISO 9001:2015", "ISO 9001:2015 risk management", "ISO 9001:2015 process approach" and "IATF 16949". The expression of the standards release year gave the assurance of getting the latest researches and articles on the standards. Several researches were studied in order to gain understanding in the field of QMS. An important aspect was to find potential challenges and benefits in implementing a QMS in organizations. Also articles on both quality standards, ISO 9001:2015 and IATF 16949:2016, included the standards' interpretations.

1.3.2 Interviews

An interview can be described as "a conversation between an interviewer and a respondent with the purpose of eliciting certain information from the respondent". Interview is a social interaction between two people aiming at increasing information level of the interviewer. Interviews can be divided into three categories: formalized (structured), non-formalized (open) and discussion. In formalized interview, the interviewer has planned and formulated the questions beforehand in a logical order. Non-formalized interview aims at as all-round view as possible. Discussion, however, can be seen as

both the interviewer and the respondent cross-educates one another to understand possible opportunities and restrictions. (Järvinen 2012)

In this research, formalized interview was conducted to find out CSR's concerning AMTM in a general level. The CSR's play a key role in organizations to comply with IATF 16949:2016 requirements. Other interviews were more or less non-formalized with the purpose to create an open atmosphere.

1.3.3 Observations

"Everyone observes the actions of others. We look at other people and listen to them talk. We infer what others mean when they say something, and we infer the characteristics, motivations, feelings, and intentions of others on the basis of these observations." (Järvinen 2012)

Observations in AMTM were conducted by examining processes and documents related to the QMS. The standards were a guideline to find the gaps between the existing documents and what are required in ISO 9001:2015 and IATF 16949:2016. Annually executed internal audits were one way to observe the QMS and the results gave valuable information. Besides all these, observations on daily based activities were conducted during the time of working on the Thesis.

1.4 Research Structure

The following Chapters present the research itself, starting with presenting AMTM where the research was done at. Chapter 2 introduces the organization's products and field of industry. In addition, customer related requirements are described, as both mentioned quality standards emphasize customer orientation.

Literature review is presented in Chapter 3. The purpose is to make the reader familiar with quality basics, quality management standards, quality audits and *Quality Management Principles* (QMP). Risk-based thinking, performance measurement, cost of quality and statistical methods are also introduced to get a deeper understanding on how the QMS can be utilized in the most effective way in organizations.

Chapter 4 presents the results. However, the results are not published in this public version by the request of the organization where this research was done. The limitations to this research are presented lastly in the Chapter 4.

Chapter 5 describes the discussion of the research results and research methods. It also includes future prospects and how the implementation process could continue. Chapter 6 contains conclusions on the research topic highlighting commitment and motivation within the organization. Conformance to requirements is discussed since certification by an external audit body is the key element in gaining the certificate.

2. AHLSTROM-MUNKSJÖ, TAMPERE MILL

2.1 Corporation and its Context

Tampere Mill belongs to Ahlstrom-Munksjö corporation. The headquarters of the corporation is located in Stockholm and production plants are situated in Europe, Americas and Asia-Pacific regions. Nearly 6,200 employees work under Ahlstrom-Munksjö corporation in 41 plants in 14 countries. (Ahlstrom InSite 2017)

The processes defined in Ahlstrom-Munksjö, Tampere Mill (AMTM) organization are top management, logistics (including sourcing), production, product development, safety, investment, process, quality assurance and the overall Quality Management System. Sales and product development processes are strongly connected to the plant, yet functioning officially under matrix organization. Information technology services, sales support services and maintenance activities are outsourced.

2.2 Products

Ahlstrom-Munksjö, Tampere Mill serves customers by manufacturing filter media roll goods for different liquid and air filtration applications. There are several product families that offer solutions to engine oil filtration, air filtration and milk filtration applications. The production method is similar to wet laid paper manufacturing. All products are manufactured by Trinitex® technology where the product is constructed of three layers offering filtration performance and mechanical properties. (Ahlstrom-Munksjö Tampere Mill presentation 2017)

The filtration products are fiber based. The fiber web is treated with binder chemical(s). Wood pulp, natural fibers (cotton), artificial fibers (viscose), synthetic fibers (polyester, bi-component polyester), mineral fibers (glass, microglass) and activated carbon are raw materials used in stock preparation. To create a uniform web, the fibers are bonded together chemically or thermally. Chemical bonding utilizes for example acrylic binder and the binder is added to the fiber web by spraying. Thermal bonding is based on synthetic bi-component fibers. (Ahlstrom-Munksjö Tampere Mill presentation 2017)

2.3 Customer Requirements

Customers have their own requirements relating to the performance of the product, in addition there are requirements concerning to cost, quantity, delivery time and shipment. Customer orientation and *Customer Specific Requirements* (CSR) play a significant role in the requirements of standards ISO 9001:2015 and IATF 16949:2016. Therefore an interview was conducted to identify and list the general customer requirements for Tampere Mill. Tero Nikander, Operational Product Manager, cleared the situation by pointing out customer expectations in the automotive sector as Tampere Mill produces filter media for engine oil and cabin air applications.

Certain customers in the automotive industry require IATF 16949 certification (former ISO/TS 16949) from its suppliers. Both cabin air and engine oil filter media produced at Tampere Mill are delivered to automotive industry, but the certification requirement is concerned especially with engine oil products. The products for automotive industry comprise about 20-30 % of the portfolio products. However, by improving the *Quality Management System* (QMS) in AMTM and meeting the IATF requirements in the overall quality system, the benefits would ultimately effect on the product portfolio fully 100 %. (Nikander 2017)

Improvement steps could be achieved by acting proactively. The main focus should be on planning carefully, preventing defects occurring for a second time and conscientiously utilizing adopted implementations. In addition, the importance in setting appropriate product specifications for the products is essential in the production and quality departments. (Nikander 2017)

New product release to commercial sales should be done more carefully. Automotive customers demand to go through a specific, procedural process which ensures that the production is able to manufacture products consistently and that the products fulfill the set specifications. Designing and manufacturing products more in co-operation with customers provides benefits saving time. Knowing detailed information about what customer wants from the product enables suppliers to fulfill the demand at once. This requires openness from both the supplier and customers and fully aligned co-operation between the two stakeholders. (Nikander 2017)

3. FRAMEWORK IN QUALITY

3.1 Quality Definitions

People see quality differently depending on their roles in the value chain of production, but the concept of quality refers overall to effectiveness (Kolarik 1999). Effectiveness can be transferred into "the state of having produced a decided on or desired effect" (Nelsen & Daniels 2007). Thus, there is no universal definition for quality, but it can mean, for example, perfection, consistency, doing a thing right the first time or total customer service and satisfaction (Evans & Lindsay 2005).

Quality also can be considered as the "goodness of the product", as defined by one of the quality pioneers, Walter Shewhart (1931) (Evans & Lindsay 2005). Joseph Juran and David Garvin – both also early quality pioneers – stated their own definitions. Juran (1970) defined quality as "fitness for use", whereas Garvin (1987) developed 8 dimensions for product quality: performance, features, reliability, conformance, durability, serviceability, aesthetics and perceived quality. (Sower 2011) The dimensions form the basis for what customers want (Evans & Lindsay 2005) and they help to determine quality through customer's eyes (Kolarik 1999).

Quality can be stated as "synonymous with 'innate excellence'" or determined as a function of a certain, measurable variable in a product. User-based perspective emphasizes what a customer expects to get and more specifically fitness for its intended use. In manufacturing perspective the "conformance to requirements" means fulfilling the wanted outcome in the activities of engineering and manufacturing. Value-based definition stands for the relationship of usefulness or satisfaction to price. (Sower 2011)

Probably the most popular definition for quality is meeting or exceeding customer expectations. The customer, however, is a broad concept. 'Internal customers' include everyone adding more value to the product within the supply chain. 'External customer' refers to the final consumer of the product. (Evans & Lindsay 2005) From the customer's point of view quality means not only meeting stated requirements but fulfilling implied requirements (Yasenchak 2016). A challenge maintaining focus in quality is to allocate resources enough achieving it (Evans & Lindsay 2005) and realizing that effective organizations talk with their customers (Summers 2005). Two of the most motivating factors are the influence of customer pressure and concern of the external image (Allur *et al*. 2014).

Customers are the foundation for most commercial organizations. They explore quality at product-based and service-based points of view. The manufacturer has to translate customer needs into product and process specifications in detail. Many organizational functions, such as design and development, marketing and engineering take part into the translation of customer needs. During the manufacturing process, even in strictly controlled conditions, unpredictable variation takes place and causes variation in the final product. For this reason the manufacturing function is responsible for ensuring to meet design specifications during the production in order to achieve intended products. (Evans & Lindsay 2005)

Delivering quality does not end in the point where the customer receives the product (Evans & Lindsay 2005). Quality means less complaints and resolving those that have been received (Yasenchak 2016). Customers may need additional services related to the product and therefore after-delivery services cannot be neglected by the quality management (Evans & Lindsay 2005).

The scope for quality is broad. *Total Quality* (TQ) gathers three targets for quality: (1) focus on customers and stakeholders, (2) teamwork and involvement of personnel in the organization and (3) continuous improvement and learning by process focus. Customers expect the company not only to meet specifications, reduce defects and resolve complaints but to design new products and answer to changing consumer demands. By allowing employees to take part in decision making, the organization relies on inherent quality and process improvement. Continuous improvement in products and processes is achieved by learning from planning, plan execution, progress assessment and examination of the assessment findings. (Evans & Lindsay 2005)

In order to gain competitive success, quality is the foundation. Competitive advantage is accomplished by rapid new product development, production and delivery flexibility and exceeding customer service. Quality-focused companies reach for increased employee participation rate and improvement in product and service quality, productivity, customer satisfaction, market share and profitability. (Evans & Lindsay 2005) One solid *Quality Mnagement System* (QMS) is a mixture of various controls, interactions, processes and resources. All mentioned aspects need to be understood and managed. (Wilson & Campbell 2016)

3.2 Quality Standards

3.2.1 International Organization for Standardization

International Organization for Standardization (ISO) is a non-governmental international organization composed of representatives from 164 national standardization bod-

ies (ISO member bodies). Its task is to gather experts to share knowledge and develop consensus-based and market relevant International Standards. ISO publishes standards which "make things work" and they offer specifications for products, services and systems to ensure quality, safety and efficiency. ISO only publishes standards. It does not provide certification or conformity assessment. An external certification body is needed for this. (ISO, all about ISO 2017)

Objective for creating quality standards is to continuously improve product quality in respect for the requirements. Standards also ensure both confidence to internal management that improvement is adapted, and that quality system demands have been realized. Furthermore, in respect for customers' and stakeholders' needs, the objective of stakeholders is to enhance the quality of operations and provide confidence to customers that delivered products fulfill set requirements. (Evans & Lindsay 2005)

3.2.2 ISO Standards

ISO publishes several standards. Table 1 reveals some of the standards that are related to QMS. The table presents the standards, year of the latest revision and a description of them.

Table 1. *Standards published by International Organization for Standardization, the latest revision year and description*

ISO Standard	**Latest revision**	**Description**
ISO 9000	2015	Quality management systems. Fundamentals and vocabulary
ISO 9001	2015	Quality management systems. Requirements
ISO 9004	2009	Managing for the sustained success of an organization. A quality management approach
ISO 10001	2013	Quality management. Customer satisfaction. Guidelines for codes of conduct for organizations

ISO 10005	2005	Quality management systems. Guidelines for quality plans
ISO 10006	2004	Quality management systems. Guidelines for quality management in projects
ISO 10012	2003	Measurement management systems. Requirements for measurement processes and measuring equipment
ISO 10014	2007	Quality management systems. Guidelines for realizing financial and economic benefits
ISO 19011	2011	Guidelines for auditing management systems
ISO 31000	2011	Risk management – principles and guidelines
ISO 37500	2014	Guidance on outsourcing

ISO 9000 family of standards consists of several standards with a different perspective, but they form an entity altogether. ISO 9000 contains the *Fundamentals* and *vocabulary* (SFS-EN ISO 9000:2015). ISO 9001 states *Requirements* and organizations can obtain third-party certification against these requirements (SFS-EN ISO 9001:2015). Organizations certified against ISO 9001 are expected to be equal to each other (Evans & Lindsay 2005). ISO 9004 offers *Guidelines for performance improvements*. It presents guidelines for performance improvement and promotes self-assessment as a core tool for organizations to measure maturity level of their QMS. ISO 9004 covers leadership, strategy, management system, resources and processes, identification of areas of strength and weaknesses and opportunities for both/either improvements and/or innovations. (SFS-EN ISO 9004:2009)

Series of quality standards offers an organization a capacity to meet challenges in constantly changing environment. Influence of quality is more large-scaled than customer satisfaction, because it can affect organization's reputation directly. The standard offers a broader way to organizations to think of their actions. Interested parties become better educated and more demanding which makes them more influential in organization's behavior. ISO 9000 emphasizes the importance of each concept, principle and their interrelationships as a whole system. (SFS-EN ISO 9000:2015)

Total Quality Management (TQM) is a broad and demanding concept. It creates the baseline for the principles of ISO 9001. Organizations can use ISO 9001 standard as a guideline with no matter of the size, industry or the country of the organization. It is up to the organization whether they choose to follow the standard with or without external supervision. (Candido *et al*. 2015) ISO 9001 states that adoption of QMS is a strategic decision for an organization. One aim of the standard is to help organizations improve their overall performance and provide a sustainable foundation for development initiatives. (SFS-EN ISO 9001:2015) "ISO 9001 views an organization as a network of manageable processes designed to satisfy customers, and includes measurable objectives, management control and documentation." Management can use manageable and controllable units as instruments to fulfill predetermined goals, strategies and visions. (de Vries & Haverkamp 2015)

3.2.3 **ISO 9001:2015**

ISO 9001:2015 is called "Quality Management Systems: Requirements". The current version of ISO 9001 was published in September 2015. Organizations certified against ISO 9001:2008 have to apply ISO 9001:2015 certification in 2018 at the latest to keep the certification. (ISO 2017)

ISO 9001 standard is a system designed to help an organization to ensure that products (or services) produced by the organization are in compliance with expressed or unexpressed customer needs and requirements (de Vries & Haverkamp 2015). To claim compliance with ISO 9001, following processes are suggested by West and Cianfrani:

- Strategic planning process must involve quality management input
- Structure and deployment in QMS in order to address challenges in globalization
- Self-assessments
- Correction, corrective action, risk assessment and improvement
- Innovation efforts
- Quality cost method
- Applying specific quality tools and methods, such as Six Sigma, Lean, TQM and *Statistical Process Control* (SPC). (West & Cianfrani 2016a)

Internal and external issues can be determined through a traditional *Strengths, Weaknesses, Opportunities and Threats analysis* (SWOT) creating at the same time a basis for strategic and tactical planning process. Organizational activities are globalized and therefore including related unique requirements, concerns and conditions create an important input to a QMS. Internal audits answer self-assessments, aiming at determination of conformity with requirements and providing information to improve processes. Implementing correction and corrective actions along with process improvement can

turn out to be powerful throughout an organization. Innovation is of high interest to top management and therefore innovation should be encouraged "by the process and not by chance". (West & Cianfrani 2016a)

ISO 9001:2015 does not require the consideration of quality costs but putting operational information into financial language can be a tool helping find actions for improvement. Again, there is no requirement for applying specific methods to be used in process deployment. However, there is a requirement that "processes are planned and carried out under controlled conditions, and it requires continual improvement". These are enhanced by the analysis of information and training staff to use data collection and analysis tools. (West & Cianfrani 2016a)

Control of QMS is achieved by "policy development and deployment, written procedures, registrations, measuring of product characteristics against requirements, measuring customer satisfaction, corrective and preventive actions, internal and external audits and management reviews" (de Vries & Haverkamp 2015). Manufacturing and administration processes, including document control, records management, supplier report cards and apprenticeships training are also included in the ISO 9001:2015 requirements. All of these aspects provide objective evidence of the organization's operations. (Yasenchak 2016)

Internal controls involve five key aspects: (1) the control of environment, (2) risk assessment, (3) control activities, (4) information and communications and (5) monitoring. All the activities must originate from the top. This is why the new ISO 9001:2015 requires top management to demonstrate leadership and commitment. In addition, there is a requirement for top management to ensure that the QMS is in line with organization's business processes and to maintain quality objectives to support the achievement of the organization's business goals. Top management is also responsible keeping the staff focused on the vision and mission, and at the same time balancing organizational priorities. Improvement of organizational operations and integrating departments and programs to work as a strong integrity are aspects that top management must emphasize. (Yasenchak 2016)

Actions of an organization should support its policy. QMS is needed to achieve this and in other words it could be stated: "say what you do and do what you say" with addition: "and (be in a position to) prove it". The promise of what an organization is able to fulfill should be the responsibility of quality assurance, and once promised the organization should deliver what was promised. (de Vries & Haverkamp 2015)

3.2.4 Changes in ISO 9001:2015 Compared with ISO 9001:2008

Some quality professionals consider that the requirements stated in ISO 9001:2008 have not changed compared with the new ISO 9001:2015 requirements. However, other quality authorities have become convinced that organizations need to change current thinking and operate differently to maintain compliance. Organizations complying the requirements of ISO 9001:2008 only at the basic level need additional work to address on-going cultural and operational actions. Culture can be defined as "the way things are done around here". Culture is linked to everybody connecting to the QMS and it is the most important in top management level. Culture changes, however, can be difficult to affect. (Green *et al*. 2015) An international survey was done prior to ISO 9001 revision process. A clear need for knowledge management was needed "related to staff turnover or not capturing or sharing information". (Hunt 2016)

The biggest changes since year the 2008 revision has been in the structure to help integrity with other ISO standards, defining the context of the organization, paying more emphasis on risk-based thinking to focus efficiently on process approach and introducing increased leadership requirements. (Medic *et al*. 2016) The main changes in the revision of ISO 9001:2015 compared with ISO 9001:2008 are (1) structure and terminology, (2) products and services, (3) understanding the needs and expectations of interested parties, (4) risk-based thinking, (5) applicability, (6) documented information, (7) organizational knowledge and (8) the control of externally provided processes, products and services (SFS-EN ISO 9001:2015).

Table 2 details the terminology used in ISO 9001:2008 and ISO 9001:2015 revisions. The purpose of revising terms is to have a coherent presentation of requirements and offer organizations a choice to use terms that suit their operations best. (SFS-EN ISO 9001:2015)

Table 2. *The biggest changes in the terms used in ISO 9001:2008 and ISO 9001:2015 (SFS-EN ISO 9001:2015)*

ISO 9001:2008	ISO 9001:2015
Products	Products and services
Exclusions	Not used (See Clause A.5 for clarification of applicability)
Management representative	Not used (Similar responsibilities and authorities are assigned but no requirement for a single management representative)
Documentation, quality manual, documented procedures, records	Documented information
Work environment	Environment for the operation of processes
Monitoring and measuring equipment	Monitoring and measuring resources
Purchased product	Externally provided products and services
Supplier	External provider

The previous version ISO 9001:2008 used terms “documentation”, “documented procedures”, “records”, “quality manual” or “quality plan” whereas the new revision states to “maintain documented information”. It is up to the organization itself what information it considers to be documented, how it is retained and what period of time it is retained. At some places, the standard states only “information” without a requirement of documenting it. In these cases, the organization can decide whether to actually document the information or not. Another change in ISO 9001:2015 revision concerns the term “externally provided” processes, products and services. The term refers to purchases from suppliers, deals with partner companies and outsourcing processes to external providers. Definition “products and services” include all output categories while often organizations provide both products and services. (SFS-EN ISO 9001:2015)

The new standard Clause of “Understanding the needs and expectations of interested parties” is for organizations to decide which interested parties are relevant to its QMS and defining the stated interested parties with their relevant requirements. An organization can review whether all the requirements in the standard are applicable to its QMS. The decision is based on the size or complexity of the organization, the management model the organization adopts, the range of the organization’s activities and the nature of risks and opportunities to be encountered. (SFS-EN ISO 9001:2015)

The 2015 version of ISO 9001 presents the concept of risk in a formal manner and more explicit way than previously and emphasizes it to be inserted throughout an organization. However, the focus is dealing risks related to product and service conformity than to customer requirements and customer satisfaction. (Chiarini 2017) Risk-based thinking is to be considered as a preventive tool even though the standard does not state “preventive action”. Preventive action is considered being inside the risk-based concept. (SFS-EN ISO 9001:2015)

A need was seen in organizations to determine the needed knowledge to make sure that processes are able to deliver products and services to meet conformity requirements. Yet, the standard does not require this information to be documented. However, objective evidence on this matter is gained through management commitment and interviews. (Hunt 2016) As Hunt pointed out and the ISO 9001:2015 states, one of the major additions to the new revision is that an organization must ensure that organizational knowledge has to be managed. Knowledge in an organization has to be managed in order not to be interfered by staff turnover or in cases of failure in capturing or sharing information. The standard encourages organizations to emphasize learning from experience, mentoring and benchmarking. (Hunt 2016, SFS-EN ISO 9001:2015)

3.2.5 International Automotive Task Force

International Automotive Task Force (IATF) operates in the automotive sector. It consists of group of automotive trade associations: Associazione Nazionale Filiera Industrie Automobilistiche (ANFIA/Italy), *Automotive Industry Action Group* (AIAG/USA), Fédération des Industries des Équipements pour Véhicules (FIEV/France), Society of Motor Manufacturers and Traders Ltd. (SMMT/UK) and Verband der Automobilindustrie e.V. (VDA/Germany). (IATF 16949:2016)

The 1st edition of the standard ISO/TS 16949 was released in 1999. The aim was to harmonize different assessments and certification systems worldwide in the automotive sector supply chain. ISO/TS 16949 introduced common techniques and methods for product and process development for automotive manufacturing. (IATF 16949:2016)

3.2.6 IATF 16949:2016

IATF 16949 standard defines QMS requirements for automotive production and relevant service parts organizations. It does not, however, work as a stand-alone QMS standard because it is supplemental and used linked with ISO 9001:2015. (IATF 16949:2016) IATF 16949:2016 mandates the use of ISO 9001:2015 which has to be obtained separately. The automotive sector, on the other hand, has full control of the IATF 16949 standard because of decoupling the automotive requirements from the ISO 9001. (Reid 2017a)

The goal of the new release of IATF 16949:2016 is to "prevent problems before they occur" with increased emphasis on operational performance and customer feedback. The new release contains many *Customer Specific Requirements* (CSR) and pays attention to executing audits to find weaknesses in the QMS of an external provider to be improved. (AIAG 2016) When compared with ISO 9001, IATF 16949 pays more attention to customer point of view providing continuous improvement, highlighting defect prevention and reduction of variation and waste in the whole supply chain. IATF 16949 should be adapted in the whole automotive supply chain, because the standard is applicable to sites where production of customer-specified production parts, service parts and/or accessory parts occur. (IATF 16949:2016)

Every company operating in the automotive industry sector has to be able to maintain product quality and deliver goods on time in competitive price to achieve customer satisfaction. The quality planning process plays an important role while it guides to effective and efficient use in the production process. Individual stages and operation processes should be designed in a way to eliminate the possibility of non-compliance. In case

non-compliances occur, efficient corrective actions have to be ensured. (Misztal *et al*. 2016)

3.2.7 Changes in IATF 16949:2016 Compared to ISO/TS 16949:2009

The new IATF 16949:2016 (1st edition) replaces the ISO/TS 16949:2009 (3rd edition). The publisher of this renewed automotive standard is IATF instead of ISO, even though there is a strong co-operation with ISO in order to continue alignment with ISO 9001. (IATF 16949:2016) In the new release, suppliers are more driven into the situation to certify their QMS to IATF 16949:2016 when compared with requirements in the previous version. Especially top management is in the key role and it must have training for IATF 16949:2016 requirements. By executing audits to top management is a way to gain objective evidence on the conformity of the QMS. Reid suggests that organizations are expected to conduct a gap analysis to find what must be addressed to fulfill the gaps. (Reid 2017b)

IATF 16949:2016 requires organizations to execute corporate responsibility, including anti-bribery policy, employee code of conducts and ethics escalations. The purpose of these requirements is to move responsibility and empowerment to all levels and functions. (Reid 2017a) The policies aim at the ethical approach and low level of reporting of unethical behavior (AIAG 2016). IATF 16949:2016 requires support processes and value-adding sites to be included in the scope of organization's QMS. Every applicable process and requirement must be included in the QMS no matter of their location. In addition, top management has to be included in the scope of the organization's QMS. (Reid 2017a)

IATF 16949:2016 requires allied and affiliated locations to be included in the scope of the QMS. Often the allied suppliers are the worst suppliers when quality and delivery issues are monitored. Usually supplier qualification, supplier selection and supplier quality are owned by sourcing function. There are new requirements to qualify suppliers by assessment and having a supplier selection process including quality and delivery performance. (Reid 2017b)

IATF 16949:2016 requires that organizations still have to have a quality manual which was cut out of the ISO 9001:2015 revision (Reid 2017b). QMS must state in which processes the CSR's are addressed. Organizations are presumed to have a process for identifying and addressing any CSR's to fulfill the critical customer requirements of the suppliers to be IATF 16949 certified. (AIAG 2016) Problems appear when *Original Equipment Manufacturers* (OEM) add their CSR to tier-two suppliers, who usually have

limited amount of resources available. IATF 16949:2016 requires an organization to meet customer requirements in full, not just address them. (Reid 2017b)

IATF 16949:2016 requires a documented process for achieving internal auditor competency in terms of QMS, product and process audits. The requirement leads to additional training needs for internal and second-party auditors, including knowledge from for example ISO 19011 and automotive core tools (Reid 2017b). AIAG states the importance to ensure that organizations educate personnel to gain the same competence to perform second-party audits, at minimum, in the same manners that internal audits are executed (AIAG 2016).

IATF 16949:2016 requires an organization to be responsible for the conformity of outsourced processes. An organization is required to address interested party needs and expectations. This means that product and process design, and validation processes have to take additional responsibilities. The interested parties' needs and expectations are expected to be effectively translated into product and process requirements in addition to validation needs and expectations. (Reid 2017a) This conformance of products ensures that an organization is responsible for the conformity of outsourced processes, and all products meet applicable requirements and expectations of all interested parties. In case of delivering nonconforming product to a customer, a new requirement is in IATF 16949 to notify the customer immediately of the occasion and follow up with detailed documentation. (AIAG 2016)

Safety-related products and manufacturing process safety are issues emphasized in the IATF 16949:2016 by requiring organizations to implement a documented process to manage product-safety related products and processes (AIAG 2106). Product safety develops pressure on product design to ensure that products do not affect harm to customers. An inherent consequence is a requirement of an escalation process with, for instance, defined responsibilities and management of safety characteristics. (Reid 2017a)

Management review has to include measures of process effectiveness and efficiency as input information. Top management is responsible for reviewing processes by evaluating and implementing improvements with process owners. IATF also states the measurement of processes in a very explicit way. Process owners are vital to assign in order to achieve the effective managing of processes. IATF 16949:2016 includes a statement that process owners have to be able to perform their role adequately. However, there is a requirement that process owners have to have the necessary competences, and both responsibilities and authorities related to the activities and results of their processes. (Reid 2017b) IATF 16949:2016 also states that an organization has to have a process for identifying training needs in terms of awareness and achieving competence for product conformity (IATF16949:2016).

ISO 9001:2015 requires "risk-based thinking" by identifying risks and opportunities whereas IATF 16949:2016 require a risk analysis including a periodic review in lessons learned from product recalls, product audits, field returns, complaints, scrap and rework. At a minimum, risks concerning products, processes and the supply chain have to be considered, but preferably an organization should implement actions to reduce or mitigate the prioritized risks based on the severity and probability of occurrence. (Reid 2017b)

Objectives are the means to push for improvement and therefore top management needs a process for cascading objectives for relevant levels and functions in an organization. There is a requirement in IATF 16949:2016 that objectives – achievable, not too ambitious – have to be established at least annually or before in case they are achieved. (Reid 2017b) IATF 16949:2016 no longer include disposal of records after a certain retention period. This is included in the ISO 9001:2015 and it thus covers the automotive standard. (Reid 2017a)

3.2.8 Benefits from Quality Management System Certification

According to ISO survey, 1.519.952 certificates were issued in the year 2015 against ISO 9001 requirements. 2.572 certifications were conducted in Finland against ISO 9001:2008 requirements whereas so far 24 against ISO 9001:2015. In the automotive sector, 17.9 % of valid certifications were in Europe in year 2016, whereas the majority of them were in Asia Pacific with 66.6 %. By August 2016, 66.033 certificates were affirmed globally and 11.820 of them in Europe. (AIAG 2016) In Finland there are only 22 sites certified against ISO/TS 16949. (ISO Survey 2017)

The potential benefits of the adoption of ISO 9001 are: (1) the ability to provide consistently products and services meeting customer and applicable statutory and regulatory requirements, (2) find opportunities for customer satisfaction improvement, (3) addressing risks and opportunities and (4) the ability to meet conformity to specific QMS requirements. (SFS-EN ISO 9001:2015) Significant improvement in performance and competitive advantage are also benefits achieved by ISO 9001 certification (Candido *et al*. 2015). Adapting ISO 9001 might create the possibility to gain growth and financial benefits to an organization. Increasing productivity and efficiency, lowering costs, improving customer experiences, increasing repeat business, sales and income, enhancing company's reputation and attracting new markets and customers are potential areas for organizations to benefit from the implementing ISO 9001. (Yasenchak 2016)

Allur states that the adoption process of ISO 9001 varies. Organizations might have similar motivations yet the use of standard may be different depending on the organization's objectives, resources and needs. (Allur *et al*. 2014) There are differences in the

motivation of implementing QMS. Some organizations might be internally motivated and aim for the implementation to gain a tool to improve performance while others want the certificate to improve the market position. (de Vries & Haverkamp 2015) With the high level of internalization it is possible to achieve bigger benefits from ISO 9001 adoption (Allur *et al*. 2014). The ISO 9001 system can have no impact, little impact or large positive impact depending on the internal motivation (de Vries & Haverkamp 2015). ISO 9001 or meta-standards and their adoption in organizations are promoted by other stakeholders in the whole supply chain. The best practices emphasize for implementation of the standards to support the improvement in day-to-day practices. (Allur *et al*. 2014)

Two organizations may be certified against ISO 9001 by using differing *Quality Management Principles* (QMP) in their daily actions. The benefits gained from adopting the ISO 9001 certified can be assessed reliably by a longitudinal study and analyzing implications of the standard. Early ISO 9001 adopters are assumed to have more mature QMS including detailed and richer adoption of the standard. Internal drivers are linked to dynamic implementation and the QMS is continuously improved. (Allur *et al*. 2014)

Surveys of the benefits after implementing and certifying have been done after a short time period after the certification. One survey was conducted by gathering longitudinal data and it showed that a high level of internalization leads to greater benefits in adopting ISO 9001. (Erlantz et al. 2014) Financial benefits can be seen in certifying the ISO 9000 standard family. However, the study of Candido *et al*. stated that organizations certified against ISO 9001 do not lead to any significant abnormal performance in decertification assuming that activities of QMS remain the same. (Candido *et al*. 2016)

Many organizations have found improvement in their performance by implementing ISO 9001 and/or ISO 14001 management systems. However, many publications emphasize that implementing and maintaining QMS create problems. The major problems are related to the bureaucratic workload it generates for organizations. In addition, lack of motivation and involvement are found to be obstacles. Rogala discovered that (1) definition and achievement of quality objectives, (2) ensuring adequate levels of staff knowledge, competence and awareness (3) proper internal communication, (4) production process, (5) the analysis of customer needs and satisfaction levels are not easy to fulfill. According to one study, only 26.6 % of the organizations certified under ISO 9001 meet the standard requirements efficiently. (Rogala 2014)

3.3 Auditing

Organization may become ISO 9001 certified when an independent agency or certification body audits the QMS of an organization (Summers 2005). Audit is ‘a systematic,

independent and documented process for obtaining objective evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled' (SFS-EN ISO 9001:2015). Standard ISO 19011:2011 does not set requirements, but provides guidance on audit program management. This standard can be applied in organizations to help executing internal, first party audits. (SFS-EN ISO 19011:2011) Executing internal audits is an indication for an effective organization to "take the time to be their own customers" and look at processes as a customer would (Summers 2005). Audit technique is critically important to obtain objectivity. During an audit interview it is essential to ask open-ended questions, truly listen to an auditee's response and to follow the audit trail which will eventually lead to the audit evidence. (Fisher 2016)

Different audit types are presented in Table 3. Audits can be characterized based on the identity of the auditor and auditee. A first party audit is an internal audit, meaning that both the auditor and auditee come from the same organization. Own organization can perform a second-party audit to a supplier or a customer can perform a second-party audit to our organization. Both situations are external audits. A third-party audit is when ISO 9001 audit is executed by an accredited registrar who has the right to accept or decline ISO 9001 certification. (Sower 2011) Third party audits for certification follow ISO/IEC 17021:2011 requirements (SFS-EN ISO 19011:2011).

Table 3. *Audit types (SFS-EN ISO 19011:2011)*

Internal auditing	**External auditing**	
	Supplier auditing	**Third party auditing**
Sometimes called first party audit	Sometimes called second party audit	For legal, regulatory and similar purposes For certification (see also the requirements in ISO/IEC 17021:2011)

Principles of auditing include: (1) integrity, (2) fair presentation, (3) due professional care, (4) confidentiality, (5) independence and (6) evidence-based approach. Integrity is the foundation for professionalism introducing, for instance, personal honesty, responsibility and ability to work in impartial manner. The fair presentation includes the idea of obligation to report truthfully and accurately. The application of diligence and judgement in auditing are due to professional care. Auditors are presumed to keep the security of information. Independence means the impartiality of the audit and objectivity of the audit results. Evidence-based approach provides a rational method reaching reliable and reproducible audit conclusions. By utilizing these principles audits provide an effective and reliable tool for an organization. (SFS-EN ISO 19011:2011)

3.4 Quality Management Principles

The seven ISO 9001:2015 QMP's are: (1) customer focus, (2) leadership, (3) engagement of people, (4) process approach, (5) improvement, (6) evidence-based decision making and (7) relationship management. The QMP's and the statements related to them are as introduced in Table 4. (SFS-EN ISO 9000:2015) Each of these seven QMP's are related to people in some way (West & Cianfrani 2016b).

Table 4. *Quality Management Principles and their statements (SFS-EN ISO 9000:2015)*

Quality Management Principle	**Statement**
Customer focus	"The primary focus of quality management is to meet customer requirements and to strive to exceed customer expectations."
Leadership	"Leaders at all levels establish unity of purpose and direction and create conditions in which people are engaged in achieving the organization's quality objectives."
Engagement of people	"Competent, empowered, and engaged people at all levels throughout the organization are essential to enhance the organization's capability to create and deliver value."
Process approach	"Consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that function as a coherent system."
Improvement	"Successful organizations have an ongoing focus on improvement."
Evidence-based decision making	"Decisions based on the analysis and evaluation of data and information are more likely to produce desired results."
Relationship management	"For sustained success, organizations manage their relationships with interested parties, such as providers."

3.4.1 Customer focus

In order to understand needs of a customer, there is a necessity for identifying who the customers are. End users, or consumers, form an important group and they are related to organization's mission and vision. However, a wider way to determine customers is to think of it in terms of customer-supplier relationships. (Evans & Lindsay 2005) For customers quality can mean: (1) characteristics of a product that satisfies stated and implied needs of a customer and (2) a product free of deficiencies (Summers 2005). Customer expectations concerning functionality can be divided into: (1) basic function, such as easy handling and aesthetics, (2) durability meaning extended use, (3) safety relating to harmlessness and (4) maintenance referring that parts can be easily replaced (Akao 1990).

Figure 1 identifies the customer-driven quality cycle where the customer needs are first collected and adopted. The needs, in other words customers' expected quality, are translated into product and process specifications. Expected quality is what the customers assume to receive. Production realizes the actual quality of the product which is delivered to the customer. Perceived quality comprises assessment of the expected quality and the actual quality. The actual quality might be inferior to what customers expect, making them dissatisfied. On the contrary, exceeding customer expectations makes them satisfied. (Evans & Lindsay 2005)

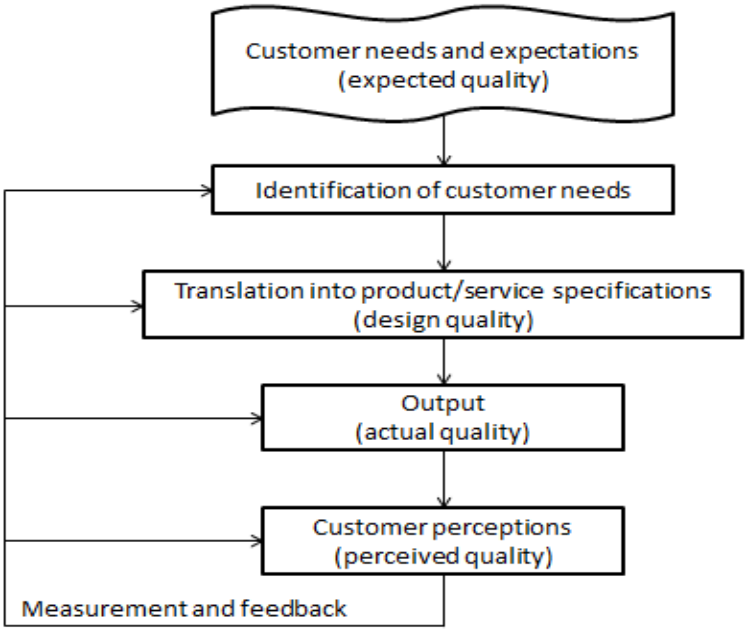

Figure 1. *The cycle of customer-driven quality (Evans & Lindsay 2005)*

Only a customer can define whether a received product or service meets the needs, requirements and expectations (Summers 2005). Customers are driven by perceived quality. Therefore, manufacturers should make sure that the actual quality conform what is expected by the customer. (Evans & Lindsay 2005) First there has to be done a determination of what product functions express the wanted quality characteristics, and next the definition of what mechanisms are needed to realize them (Akao 1990).

Not to make it too easy, customer perceptions may vary under time (Evans & Lindsay 2005) or a customer might not be able to state requirements clearly (Summers 2005). Chiarini discovered that at times customer requirements are not translated as well as they should be. This might lead to problems in design and production processes. In addition, use and management of quality methodologies and tools, such as *Quality Function Deployment* (QFD), should be introduced to sales and marketing personnel as well. (Chiarini 2017) To manage the complexity of customer expectations, a customer satisfaction measurement should be introduced in the organizations along with the usage of customer feedback for improvement (Evans & Lindsay 2005). Organizations need loyal customers. A customer compares pros and cons of all available options and purchases the most valuable option to its need. (Summers 2005)

Customer focus in knowledge perspective, requires a broad process framework by clear communication and consultation and include suppliers and customers in the organization's activities (Wilson & Campbell 2016). ISO 9004:2009 suggest organizations to collaborate effectively with customers and create mutual beneficial relationships (SFS-EN ISO 9004:2009). By improving communication channels and introducing feedback systems it is possible to eliminate dissatisfaction and improve customer satisfaction (de Vries & Haverkamp 2015). In order to decrease the possibility to deliver nonconforming products to customers, customers should participate in reviewing and controlling product design results (Chiarini 2017).

Customers are not only external customers outside an organization. There are customers inside an organization because each employee receives input(s) from previous stages and creates output(s) for next ones. The importance of better understanding everyone's roles is essential in order to satisfy both internal customers and externals. Effort should be put in well-being and growth opportunities for all employees. (Evans & Lindsay 2005) ISO 9000:2015 states that by, for example, (1) recognizing all customers who bring value to organization, (2) linking the organizational targets together with customer needs and expectations and (3) communicating the needs and expectations of customers throughout the organization might have action to improve customer focus in organizations. In addition, it might be valuable to measure customer satisfaction and execute necessary actions related to the results. (SFS-EN ISO 9000:2015)

3.4.2 **Leadership**

ISO 9001:2015 emphasizes more attention to leadership and management commitment. Top management must engage in taking responsibility for the effectiveness of the QMS – unlike in the ISO 9001:2008 version it was addressed only on the Quality Manager's shoulders. Quality on the ISO 9001:2015 version is considered a matter for everybody and at all levels, referring to originally the Japanese idea of TQM. (Medic *et al*. 2016) Clause 5 "Leadership" in ISO 9001:2015 introduces the importance of leading the organization and its people. There is a long list of responsibilities and activities for organizational managers and top management. Much of these can be delegated but quality professionals should help top managers to decide which of them they should personally execute and which to assign to others. The decision of the dividing should be done carefully, though. This is also a place for the quality professionals to grow their skills in learning the language of finance to improve the communication with top management. (West & Cianfrani 2016b)

Quality planning should be in conjunction with mission and vision statements. In addition, the policy and objectives should be in alignment with business plans. Otherwise it will be challenging to achieve high and sustainable performance levels. The key to gain real success comes from full alignment planning in the organization. Besides the involvement of people in every level at the organization, the alignment requires knowing and understanding how the day-to-day activities affect on achieving the set objectives. Team leaders are responsible to deliver the message of individual importance, team performance and continuous improvement. (West & Cianfrani 2016b)

The concept of leadership set a need for an environment of enabling people to apply policies, processes and resources so that quality goals can be achieved. Providing strategic vision, communicating, motivating, delivering change and focusing on the knowledge agenda are the driving forces to a knowledge leader. (Wilson & Campbell 2016) Individual leadership emphasizes maintaining focus and discipline to complete jobs consistently, proactively participate in problem solving, targeting at win-win situations and taking continuous learning as a personal habit. Personal skills, such as, vision, empowerment, intuition, self-understanding and value-conformity are associated to leaders. Prospecting to the future and visioning in the changing environment is crucial. (Evans & Lindsay 2005)

By allowing employees in all organizational levels to act as leaders creates an environment of development and increase in emotional intelligence. Self-awareness, self-regulation, motivation, empathy and social skills are important features of employee abilities. In order to achieve total quality success, all managers must support developing skills, investing in teamwork and participation, motivating and recognizing employees and creating significant communication. The leading practices in human resource management involve communicating total quality with all employees, highlighting team-

work, emphasizing in “make a difference” –attitude and make reward and consolidation systems available. (Evans & Lindsay 2005)

ISO 9000:2015 points out the importance to create and maintain shared values in addition with encouraging an organizational commitment to quality and ensuring that all leaders show a positive attitude in the organization (SFS-EN ISO 9000:2015). There is also seen that “crucial role of optimistic leadership and management is delighting customers”. In reality, this means that employees have to come to work with joy, because “highly engaged employees keep customers delighted”. The choice of positivity is seen more rewarding, engaging, inspirational and enjoyable. An organizational culture of optimism and embedded joy is built on can-do attitude and affirmative business design in the daily work operations. The same attitude should happen with planning standard implementation to be equally optimistic and enriching. (Ramu 2017)

3.4.3 Engagement of People

Implementation of ISO 9001 cannot reach to internal benefits without internal motivation and accomplishment. The effective utilization of *Human Resources* (HR) can be gained by involving people in all organizational levels to utilize employee skills and knowledge. The utilization requires a will from the HR process and implementation of strategic HR management practices. (Rogala 2014) The engagement of people could be improved by supporting active collaboration and promoting open discussion and knowledge sharing, as stated in ISO 9000:2015. (SFS-EN ISO 9000:2015)

ISO 9001:2015 considered the first time organizational knowledge as a resource. The distinction between *Knowledge Management* (KM) and *Quality Management* (QM) is not radical, because they share the same elements aiming at enhancing organizational performance. In addition, they both complement improvement, competitive advantage and offer a tool for a wide concept of organizational development. (Wilson & Campbell 2016) The KM approach consists of five components: identify, create, store, share and apply. Organization’s process knowledge depository lies in the quality manual and it is achieved by learning from experience, mentoring and benchmarking. (Wilson & Campbell 2016)

A quality system must balance between applying systematic control to achieve set quality outcomes and subjective, tacit knowledge by the employees. Organizations should put more emphasis on recognizing tacit knowledge. Knowledge gathering is a combination of believes, judgements, messages and representation, values and wisdom. Figure 2 represents the knowledge pyramid with different levels of how broad the way of thinking is. Data creates the basis, evident-based level. Analysis of the data becomes information and involves a broader way to deal with the subject. Knowledge on the oth-

er hand is a basis for decision-making and it aims at desired results. Decision-making is a complex process where uncertainty is always present. Facts, evidence and analyzing end up in better decisions and in years of experience wisdom can be achieved. (Wilson & Campbell 2016)

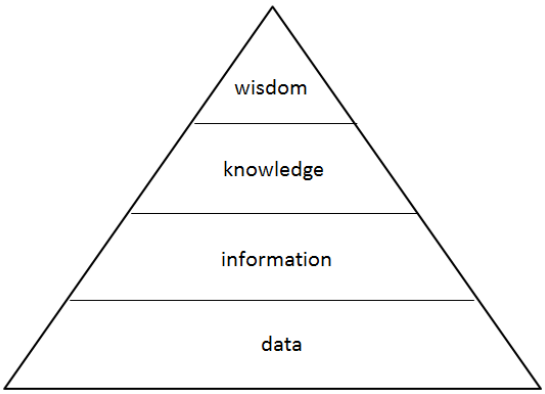

Figure 2. *The knowledge pyramid (Wilson & Campbell 2016)*

ISO 9001:2015 expects the knowledge in the organization to be distributed effectively and efficiently to all relevant parties inside and outside the organization. However, the concept of tacit knowledge is abstract and thus difficult to manage and attach to processes and systems. (Wilson & Campbell 2016) Imperfect training might create potential risks ending up in nonconforming products and customer dissatisfaction (Chiarini 2017). Yet, risks related to the loss of knowledge arising from employee turnover and unsuccessful share of information are vital to understand (Wilson & Campbell 2016).

Conformance to standards means that the advice of others is followed implicating in certain loss of one's freedom of choice and self-control. This is why there is certain reluctance to follow standards to be expected. Psychologists underline that there is human resistance against control. "Standardization is often seen as an unwelcome, unnecessary, and harmful intrusion into a world of free, distinct individuals and organizations that are wise enough to decide for themselves." Standardization means regulations coming from outside. The challenge is that particularly management systems affect human behavior more straightforward than technical standards. (de Vries & Haverkamp 2015)

Employee behavior becomes transparent by described processes, subsequent measurements, evaluations and audits. Both the employee and manager are captured by the system and it is not a surprise that there may be feelings of resistance. "The quality management system exercises normalizing power. It is an instrument of discipline." (de Vries & Haverkamp 2015) However, the ownership of problems and opportunities, and proactively implementing improvements can be assigned to employees. Self-understanding demands exploration of one's both weaknesses and strengths. Value be-

comes an important feature in terms of combining one's values into the organization's management system. (Evans & Lindsay 2005) Organizations are essential for identity and well-being of individuals. The discussion and negotiating all elements of the QMS and the system itself are important ending up in transparent communication and arriving in consensus. (de Vries & Haverkamp 2015) Garvin stated that sharing knowledge must become a norm and value to a company and thus emphasizing to move from the old fashioned thinking "knowledge is power" (Evans & Lindsay 2005).

Organizations utilizing mechanistic and explicit knowledge tend to have a better compatibility with ISO 9001 requirements than organizations using more tacit knowledge. Organizations with tacit knowledge approach may lack in inclusive documentation which could be found as weakness by the quality auditor. There is a clear difficulty in organizing and measuring deeply embedded tacit knowledge accurately and systematically. (Wilson & Campbell 2016)

3.4.4 Process Approach

By adopting a process approach to an organization it is possible to understand and consistently meet requirements. Process approach considers processes with respect to added value, helps to achieve effective process performance and support to improve processes based on the assessment of data and information. (SFS-EN ISO 9001:2015) It is fundamental to design and manage effective processes through the whole value chain, like manufacturing, order entry, product design and customer service. This brings managers along with employees in the presence of designing and improving of processes. (Evans & Lindsay 2005) Still, on daily basis, some customer products become more urgent than others, which trouble production planning and control, and might have severe effect on the performance of on-time delivery and customer satisfaction (Chiarini 2017).

Process design starts with process identification and documentation. An effective process design concentrates on the prevention of bad quality and fulfilling the requirements of both internal and external customers. In addition, the process is expected to be capable at the planned performance level. A process has to be both repeatable and measurable. Repeatability means that the process is able to gain the same performance level over time. Measurability means that essential quality and performance indicators of the process can be provided. Process owners are responsible for managing and improving their process. (Evans & Lindsay 2005) In ISO 9001:2015 there is a requirement to develop or modify the organization's existing processes. The recognized processes should include both strategic and tactical planning. (West & Cianfrani 2016b)

"A process exists when: (1) its output is identifiable, (2) its input and steps to achieve the output are recognized, and (3) the ownership of that output and process has been

assigned" (Fisher, 2016). The principle of a separate process and its elements is shown in Figure 3. In order to control the process activities, it is necessary to monitor and measure check points. The controls are specific with each process and vary based on the risks related to it. (SFS-EN ISO 9001:2015)

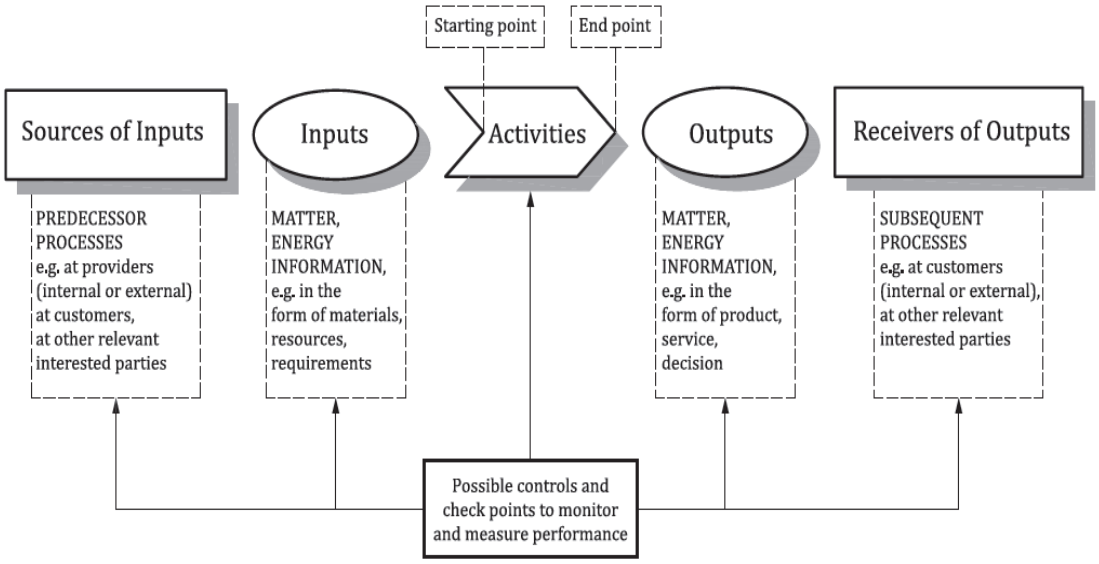

Figure 3. *The elements of a separate process (SFS-EN ISO 9001:2015)*

The *Plan-Do-Check-Act cycle* (PDCA) can be applied to individual processes or the QMS as a whole. The PDCA cycle is presented in Figure 4. Numbers in brackets refer to the standard clauses. Clause 4 "Context of the organization" included in the QMS is based on the identification of the operational context – scope and processes – and all interested parties with their requirements as well as customer requirements. Organization's QMS foundation consists of the engagement of people and "Leadership" stated in Clause 5. Leadership affects all other activities: "Planning" in Clause 6, "Support" in Clause 7, "Operation" in Clause 8, "Performance evaluation" in Clause 9 and "Improvement" in Clause 10. Organization's QMS accomplish products and services which creates customer satisfaction level. This altogether give the esults of the organization's QMS. The results must be taken into consideration in terms of any changes needed in the QMS to improve the results and customer satisfaction. (SFS-EN ISO 9001:2015)

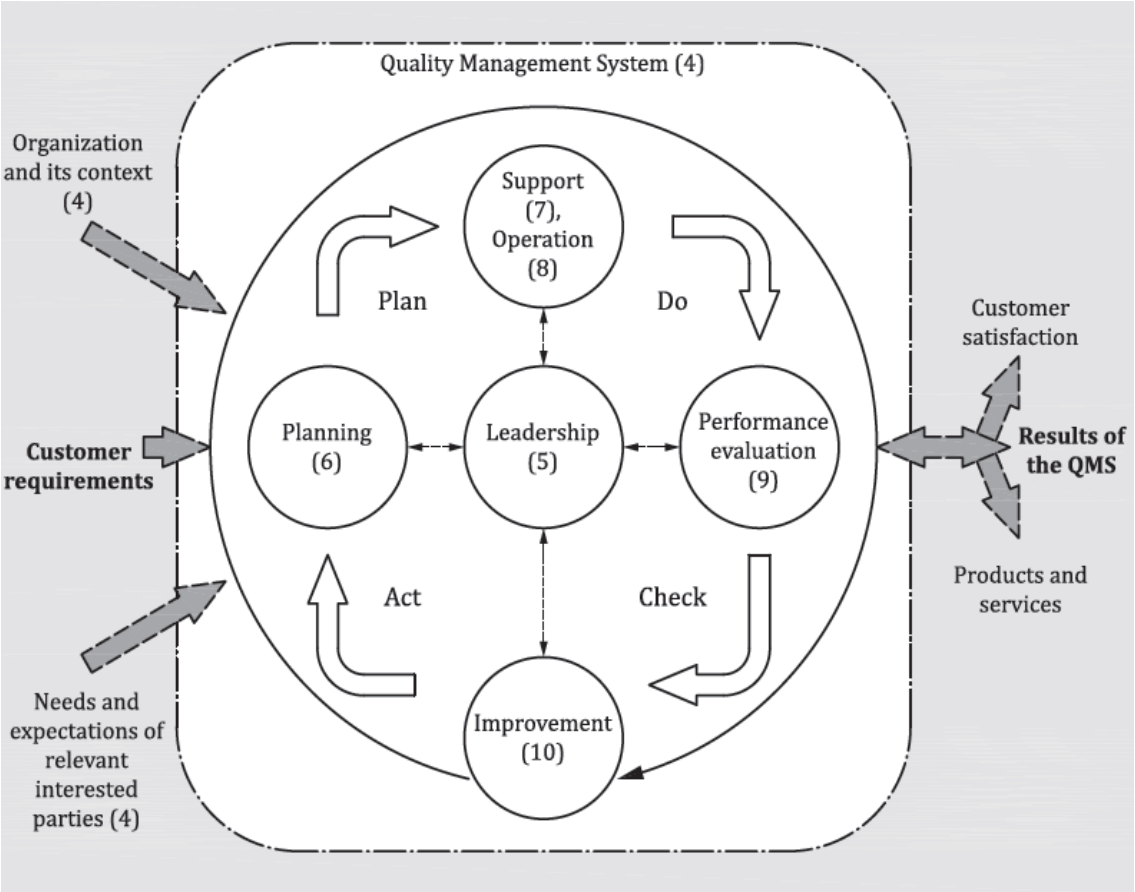

Figure 4. *The interactions of a PDCA cycle in organizational processes and its relation to standard Clauses (SFS-EN ISO 9001:2015)*

In the PDCA cycle, planning involves Clauses 4-7 pointing out that the actions of organizations must be planned based on the information gathered from the determination of the context and relevant interested parties. In addition, actions related to leadership including creating a quality politics, emphasizing customer orientation and determining roles for personnel working for the organization have to be planned to achieve intended outputs. A part of planning is to assess risks related to organization's operations, setting objectives for its QMS and planning changes. Support functions – people, infrastructure, monitoring and measurement resources, organizational knowledge, competence, awareness, communication and documented information – are also an important part of planning in the PDCA cycle. (SFS-EN ISO 9001:2015)

Clause 8 "Operation" is the actual implementing of what was planned and it is realized in the do-phase in the PDCA cycle. Do-phase is a combination of operational planning and control, requirements for products, design and development of the products, the control of externally provided products and services, production provision, the release of products and control of nonconforming products. (SFS-EN ISO 9001:2015)

In the PDCA cycle the check-phase contains monitoring, measuring, analyzing and evaluating of processes, products and services, executing internal audits and conducting management reviews as stated in Clause 9 “Performance evaluation”. The above mentioned actions are taken to set policies, objectives, requirements and planned activities and taking effectiveness, efficiency and risks into account. The final stage of the PDCA cycle is the act-phase and covers the clause 10 “Improvement”. It includes taking actions to enhance performance, if necessary. It takes nonconformities and corrective actions related to them into account with continuous improvement. (SFS-EN ISO 9001:2015)

Organizational leaders in quality and customer satisfaction are suggested to follow the next practices in their operations:

- The essential determination and documentation of value in processes and managing the processes
- The success in translation of customer requirements into product and process design specifications in early stage and taking into account links between product design and process requirements, supplier capabilities and both legal and environmental issues
- Making sure that quality is built into products and meaningful engineering, tools and approach are used during the development process
- Product development process is managed by taking into account cross-functional communication, reducing time of product development and ensuring production launches without problems
- Determining performance requirements for suppliers and ensuring that they are fulfilled, in addition, developing partnerships with key suppliers and other organizations
- Controlling quality and operational performance of key processes, using systematic ways of identifying major variations in operations and output quality, determining root causes, making corrections and verifying results
- Continuously improving processes to enhance better quality and overall operational performance
- Using approaches as benchmarking and re-engineering to get breakthrough performance (Evans & Lindsay 2005)

Process control is the activity to ensure conformance to requirements. In case of nonconformity, corrective actions are taken to fix problems and maintain stable conditions. Process control is important, because it is a basis for both effective daily process management and long-term improvements. Control consists of setting a standard or objective, ensuring a way to measure output and finally comparing the actual result(s) with the standard along with feedback got from the corrective action. (Evans & Lindsay 2005) Many quality problems are related to process malfunctioning rather than human

involvement. Better quality and enhanced organizational performance can be gained by preventing both defects and errors and eliminating waste. (Evans & Lindsay 2005)

In case of manufacturing processes, control is typically set in incoming materials, key processes and final products. Organizations adapting TQ philosophy should push the compliance of requirements to the suppliers' responsibility. The heavy inspection of incoming raw material should not be performed by the customers. Instead, the suppliers are expected to give statistical evidence to fulfill set requirements along with customers executing only occasional inspections of incoming materials. (Evans & Lindsay 2005)

3.4.5 Improvement

Implementation of a QMS is not worthwhile to comply superficially, but to aim at surpassing requirements. "A competitive market needs more than compliance. It needs differentiation". (Ramu 2017) In order to be successful it is essential to response to both internal and external changes. Explicit knowledge is easier to manage, yet process improvement process is linked to a combination of technical and socially oriented knowledge creation. Commercial success can be gained through tacit knowledge to create competitive advantage. Tacit knowledge is captured in an explicit way in operational manuals and processes. However, tacit knowledge which is elusive may offer a greater value and it might be more valuable in finding operational failures. (Wilson & Campbell 2016)

Figure 5 represents an extended model of a process-based QMS with the elements of ISO 9001 and ISO 9004. Organization's QMS should be based on QMP's. (SFS-EN ISO 9004:2009)

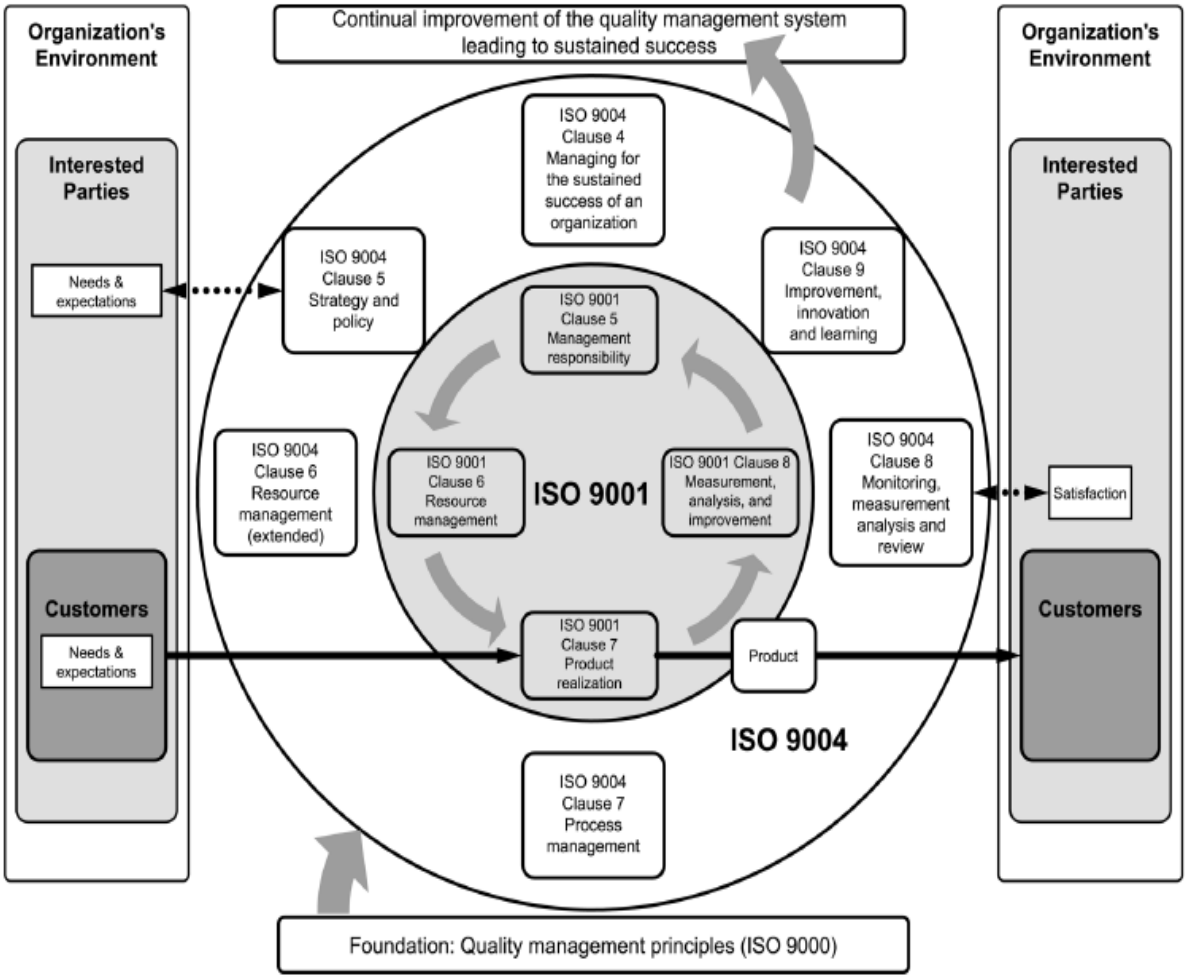

Figure 5. *An extended model of process improvement in organizational activities (SFS-EN ISO 9004:2009)*

3.4.6 Evidence-Based Decision Making

Decision making should be based on objective examination and evaluation of data and information. Decision making, though, is complex and uncertain requiring subjective reading. In other words, tacit knowledge can assist and support decision making. Data and information create a basis for knowledge in KM, but they are not knowledge. Data and information are objective measures, but they become knowledge by mentally processing and applying them. (Wilson & Campbell 2016)

3.4.7 Relationship Management

The concept of relationship management requires an organization to interact with interested parties. The KM cycle should be broader taking, for example, suppliers and customers, into account. Traditionally, the suppliers have been a part of the supply chain but also customers have a great role by holding the depository of knowledge. (Wilson & Campbell 2016) Despite the identification of suppliers in the supply chain, organizations seem to have quite low control over their supplier processes, yet recognizing that inspection on supplier products increase the cost and slow lead time. Thus, a deep supplier evaluation should be conducted especially at the beginning of the business relationship and not being blind to cheap price or a faraway country. (Chiarini 2017) Knowledge of relevant stakeholders which may provide benefits must be identified and research must be conducted to enable innovations. Tacit and explicit knowledge must be identified within both the organization and externally including the suppliers and customers. (Wilson & Campbell 2016)

ISO 9001:2015 states in Clause 4 "Context of the Organization" for organizations to understand the relevant interested parties and their needs and expectations. Clause 4.1 challenges organizations to think strategical and tactical levels in its QMS. The organization's ability to achieve intended results must be reviewed through identifying and monitoring relevant internal and external issues. Clause 4.2 requires a determination of interested parties that are relevant to the products manufactured and the search of their requirements. (West & Cianfrani 2016b)

Organization's context is a combination of internal and external issues that have an effect of its investments and ability to produce products and services. Context can include (1) specific objectives, (2) customers' any other relevant interested parties needs and expectations, (3) products and services, (4) the interaction and complexity of organization's processes and (5) size and organizational structure. The basic idea is to recognize the positive and negative, relevant internal and external factors, monitor them on a continuous time scale and assess whether they have an impact on the organizations QMS. Auditors are responsible to research the organization's environment before audit to challenge whether essential factors have been identified and their possible impact on organization's activities. (Medic *et al*. 2016)

3.5 Risk-Based Thinking

In order to achieve effective results in the QMS, it is important to utilize risk-based thinking in an organization by planning and implementing actions related to considering risks and opportunities. Benefits to addressing risks and opportunities end up in improved results and the prevention of negative effects. (SFS-EN ISO 9001:2015) Risk is

considered to be linked to potential effects and it may be applied in any function in an organization, including planning. The risk-based thinking approach is aiming in preventive management system (Medic *et al*. 2016) and it can be applied to the whole organization in any area or level, at any time and to any specific function, project or activity (SFS-ISO 31000:2009).

ISO 9001:2015 requires organizations to recognize relevant issues, determine risks and opportunities in Clause 6.1 "Actions to address risks and opportunities" (SFS-EN ISO 9001:2015) because "all activities of an organization involve risk" (SFS-ISO 31000:2009). However, the most relevant risk according to Chiarini study was the managing of several resources – workers, equipment, machines, instructions and materials – related to production processes (Chiarini 2017).

The purpose of these identifications is to plan the QMS so that the organization is able to achieve the intended results, prevent or mitigate undesired effects and accomplish improvement. (West & Cianfrani, 2016b) The risk and opportunity action plan can include: (1) avoiding risk, (2) eliminating the risk source, (3) changing the likelihood or consequence, (4) sharing the risk, (5) taking risk by informed decision and (6) taking risk to chase an opportunity (Medic *et al*. 2016).

Risk-based thinking in a process can mean considering "how the negative consequences of the risks are addressed to minimize the impact and at the same time how the positive consequences to interested parties can be maximized" Often risks and opportunities are cited together, but opportunity is not the positive side of risk. "An opportunity is a set of circumstances which makes it possible to do something. Taking or not taking an opportunity then presents different levels of risk." (Ramu 2017) Opportunities can appear related to favorable situations where intended results have been achieved. Deliberation of associated risks can be contained in the actions addressing opportunities. Uncertainty creates risks which can have either positive or negative effects. A positive difference appearing from a risk can contribute an opportunity, but not all of the positive differences end up in opportunities. (SFS-EN ISO 9001:2015)

Organizations should orientate more on recognizing possible opportunities more efficiently. Ramu also challenges organizations utilizing *Failure Mode and Effect Analysis* (FMEA) to score a similar measure for opportunities than there is for assigning risk priority numbers. Once the scoring of opportunities has reached a certain level and perhaps they impact positively, for instance, to customers with higher profitability in short timeframe, there are reasons to refine priorities, especially when the costs of implementation are added. (Ramu 2017)

The effectiveness of actions to address risks can be done by audits and internal reviews, KPI analysis and project evaluations, but the most important thing is to have the right data available. In an improved risk function in organization it is possible to achieve effi-

ciency, reduce the probability of losses, gain improved strategic decision making and get better profitability. Organizations get the possibility to understand the QMS and control of 'the culture of compliance' by researching audit reports, customer complaints, nonconformance and document notification confirmations. (Medic *et al*. 2016)

3.6 Performance Measurement

Financial or accounting indicators are not solely enough for decision making. Overall organizational targets meeting or exceeding customer expectations and utilizing limited resources effectively are accomplished by gathering good data. The information should be collected of customers and markets, human resource effectiveness, supplier performance, product and service quality and other relevant key factors. A broad gathering of performance information ensures a more comprehensive view for business performance. Organizations have to understand things that are present at the moment as well as things that might happen in the future. (Evans & Lindsay 2005)

A measure is the criteria, metric or means where output is compared with. A metric, is defined as a standard for measurement. The 'voice of the customer' inside an organization is vital. This provides the certainty that customer concerns and priorities are taken into account in decision making. Two things must be carefully considered relating to collecting customer input: validity and reliability. Validity describes the level of the method being used to measure what it was intended to measure whereas reliability describes the functioning without failure under certain periods of time. (Sower 2011) To create beneficial process performance measurement requires five things: (1) identifying customers and their requirements, (2) defining the work process, (3) defining the value-added activities and outputs, (4) developing specific performance measures and (5) evaluating the performance measures to make sure their usefulness. (Evans & Lindsay 2005)

Customer satisfaction can be indicated by measuring cycle times and both product and service quality. Performance levels of products and services that effect on customer satisfaction are important for the organizations to define. Financial measures might include revenue, return on equity, return on investment, operating profit and other liquidity measures. One useful measure is cost of quality. Another critical point is human resource measurement, because it has an influence on achieving quality and performance objectives. Designing the system for performance measurement must be done carefully in order to gain overall health for the organization and support daily decision making. (Evans & Lindsay 2005)

3.7 Cost of Quality

Cost deployment aims at building engineering processes systematically in order to reduce product cost and still maintain a balance with quality (Akao 1990). The cost of quality is considered any cost that is related to guaranteeing perfect products or services. The prevention of poor quality is also included in quality costs. As seen in Figure 6, for example scrap, rework, mistakes and waste are considered as quality costs. These are easy to identify, but they form only the iceberg top of all quality costs. (Summers 2005)

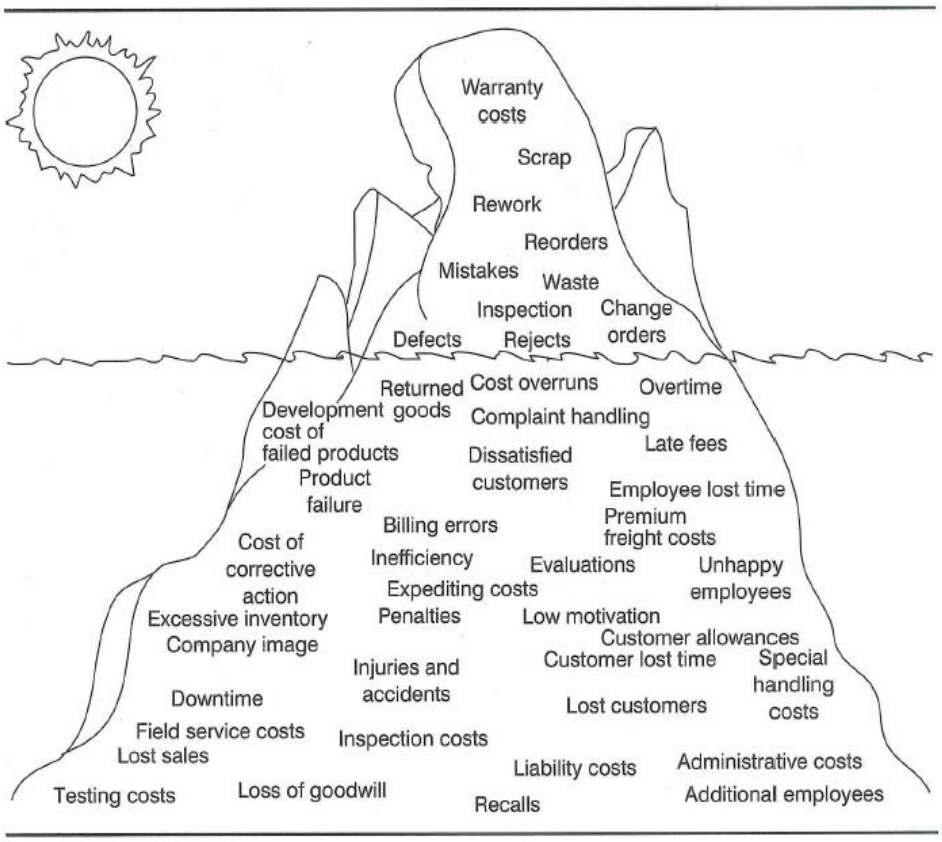

Figure 6. *The Iceberg of Quality costs (Summers 2005)*

The cost of quality is a broad concept, being usually 20-40 percent (%) of sales. Quality costs are not related only to manufacturing but also other activities, including for example purchase and customer service departments, create them. In addition, number of costs are related to poor quality which could be avoided. The problem in not managing the avoidable poor quality costs is in connection with not assigning proper responsibility for relevant, structured actions. (Sower 2011) In addition, blind cost reduction might cause more problems than it solves (Akao 1990).

For categories creating quality costs can be identified: (1) prevention costs, (2) appraisal costs, (3) internal failure costs and (4) external failure costs. Prevention costs disable nonconformity products to appear in the first place. It includes quality planning, process control, information systems and training. Appraisal costs are securing the conformity of products by test and inspection activities, instrument maintenance and process measurement and controls. Internal failures are found before the product is sent to the customer and the costs related to this come from, for instance, scrap and rework, corrective actions, downgrading and process failures. External failure costs come after the customers receive nonconforming products. The costs can be related to customer complaints and returns, product recall and warranty claims and product liability. (Sower 2011)

Researches state that focusing on prevention actions can create large savings because less nonconforming products are manufactured (Sower 2011). ISO 9001 emphasizes continuous improvement recognizing that waste is money loss and waste is a result of poor quality and inefficiency. Inefficiency, on the other hand, comes from variation and inconsistent processes. (Yasenchak 2016)

If faulty products end up to the customer, the costs related to the error increase. The company delivering nonconforming products or services will suffer from reputation problems. Preventing the nonconformity product or service before sending to the customer is less expensive. Possible difficulties should be identified and effort put in during the design and planning phase. (Summers 2005)

Product planning, product design, prototyping and pre-production create issues to solve in organizations in terms of quality and cost. Imprecise cost targets, lack of cost deployment, lack of understanding cost prediction, poor evaluation of cost prediction and imprecise measures for cost reduction targets are problems that might occur. These reflections might appear because of rough quality targets, imprecise sales point, inadequate quality prediction engineering, weaknesses in determining quality level, poor communication and poor understanding about process capability. (Akao 1990)

Organizations should attend to identifying the financial returns on quality-related investments. The benefit is to notice that things are made correctly but also to recognize if the path is wrong and still corrective actions and improvements could be done before proceeding to far. Additional attention should be paid in external factors including accounting revenues related to customer satisfaction and improved quality. (Sower 2011)

3.8 Lean Six Sigma and Statistical Process Control

3.8.1 Lean Six Sigma

Six Sigma is a method for implementing improvements and gain excellent performance levels that take into account factors that are relevant to customers and both identifying and eliminating things that cause errors or defects in processes. The implementation of Six Sigma requires the introduction of statistical and other tools identifying quality problems. The goal using Six Sigma is to gain breakthrough enhancements that provide value to the organization itself and customers by using problem solving techniques. Usually systematic fact-based, often statistical methods, are introduced. (Evans & Lindsay 2005) Better results are achieved by implementing Lean and Six Sigma together than solely. Lean concept with principles and tools focuses on enhancing process speed and reducing waste. Six Sigma, on the other hand, aims at minimizing variation to prevent defects. Six Sigma involves statistical reasoning. (Marques *et al*. 2016)

Six Sigma should be applied at two levels: one in macro (managerial) level and the other in micro (operational) level. The macro level integration should be done by linking Six Sigma with QMP's. Micro level connects the Clauses of ISO 9001 with the *Design-Measure-Analyze-Improve-Control* (DMAIC) roadmap. (Marques *et al*. 2016)

Lean Six Sigma projects go through a common project life cycle regardless of the methodological approach: (1) project identification, (2) project selection, (3) planning, execution and completion of the project and (4) post-project. Figure 7 presents a proposed integration framework for project life cycle stages with clauses in ISO 9001:2015. The first two stages (project identification and project selection) appear from opportunities for improvement and for innovation. (Marques *et al*. 2016)

Every selected process has to be planned carefully before executing. Project goals must be aligned with quality objectives. Another aspect is to anticipate, prevent and mitigate risks. Each selected project is executed according to the most suitable roadmap. In the post-project phase it is essential to assess of how much the identification of risks and opportunities had affected the project results. The support of the lessons learnt after completing the project should act as an input to future projects and improvement of the whole QMS performance. (Marques *et al*. 2016)

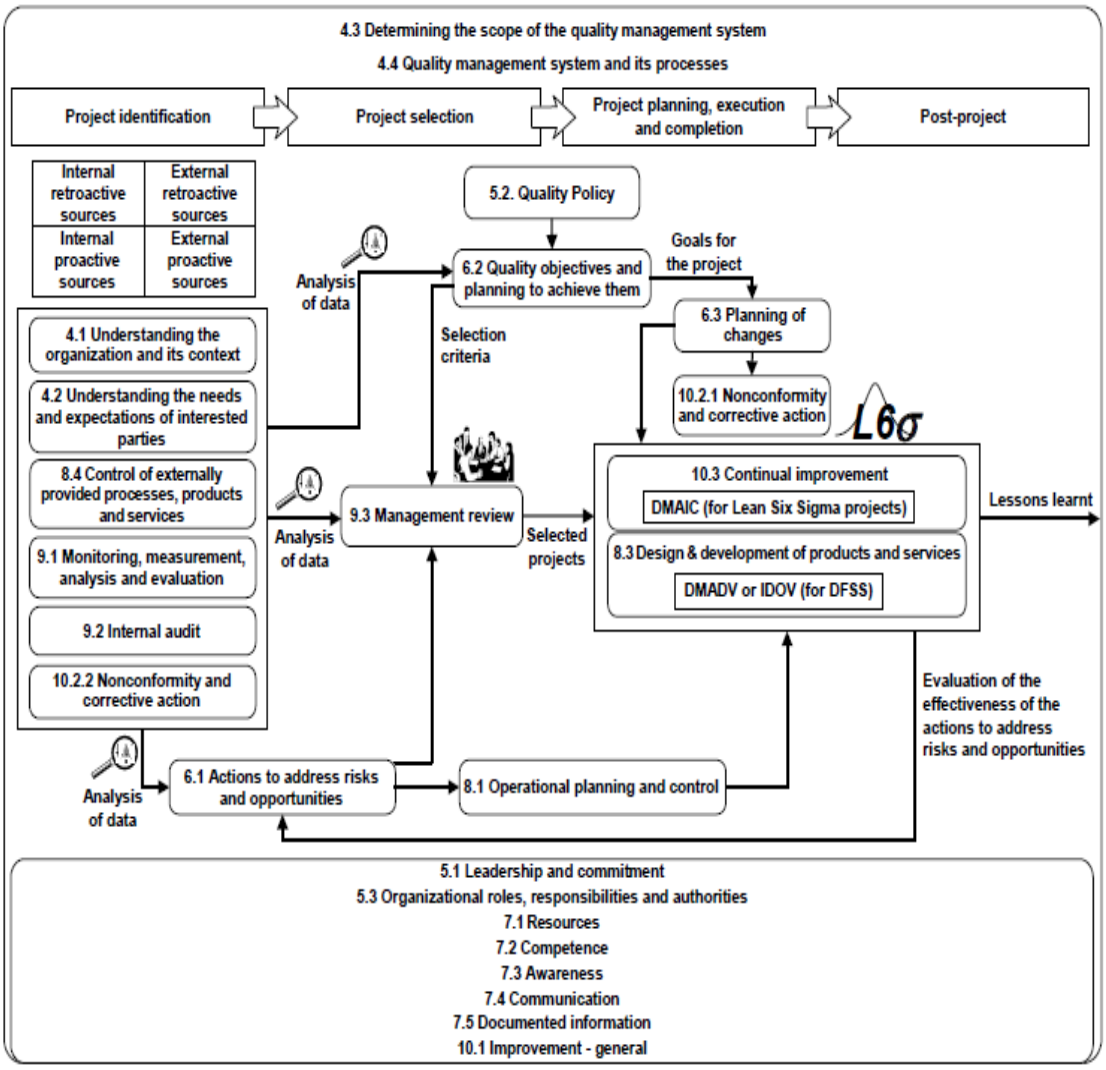

Figure 7. *A model to integrate Lean Six Sigma together with ISO 9001:2015 (Marques et al. 2016)*

The decision of potential project execution is based on analysis of data, which can come from several sources: internally, externally, retroactively or proactively. Table 5 contains different sources of data which can be derived from any of four sources. However, there is a miss spelling in the source of data on the right hand side. The source of data is supposed to be external source instead of internal source. Usually, data is received from clause 4.1, 4.2, 8.4, 9.1, 9.2 and 10.1 activities. By gaining knowledge of the most frequent and severe nonconformities it is possible to identify opportunities for improvement and thus detect potential projects. Previous root cause analyses made for nonconformities, implemented corrective actions and evaluations of their effectiveness can also help. Identification of risks and opportunities can be helpful for organizations to scope potential Lean, Six Sigma and *Design for Six Sigma* (DFSS) projects. (Marques *et al.* 2016)

Table 5. *Different sources of data for potential project discovery (Marques et al., 2016)*

	Internal source of data	Internal source of data
Retroactive sources of data	• Key performance indicators (KPIs) results • Available internal audit reports • Corrective action records • Nonconforming product reports • Historical results regarding the evaluation of external providers	• Results from customer satisfaction surveys • Customer complaints and claims • Available documents (e.g. studies, reports, surveys) published by external entities (e.g. regulatory bodies, consumer associations)
Proactive sources of data	• Internal brainstorming sessions • Conduction of *gemba* walks • Improvement suggestions from workers	• Competitive benchmarking studies • Interview sessions with customers • Focus groups sessions with external stakeholders

3.8.2 **Statistical Process Control**

Statistics is a science dealing "the collection, organization, analysis, interpretation, and presentation of data". Statistical concepts and their importance in QM cannot be over-emphasized and they play a key role in continuous improvement philosophy. However, knowing statistical methods and tools is not enough; managerial decisions must be based on understanding the role of science of statistics and managers need to think statistically. (Evans & Lindsay 2005)

Statistical thinking requires understanding that all work happens within interrelated process systems, and realizing that variation is present in each process, but a path to success is to reduce variation. Variation comes from many sources, as seen in Figure 8. Variation appearing, for example in materials, tools, machines, operators and environment, are called common causes and these natural parts of processes can be statistically predicted. Common causes make up to 80 to 95 % of total variation in the output of the production process and can be removed only by redesigning the product, or by introducing better technology or training. The rest of the variation is present because of special, external causes (or assignable causes) which are not inherently part of the process. (Evans & Lindsay 2005)

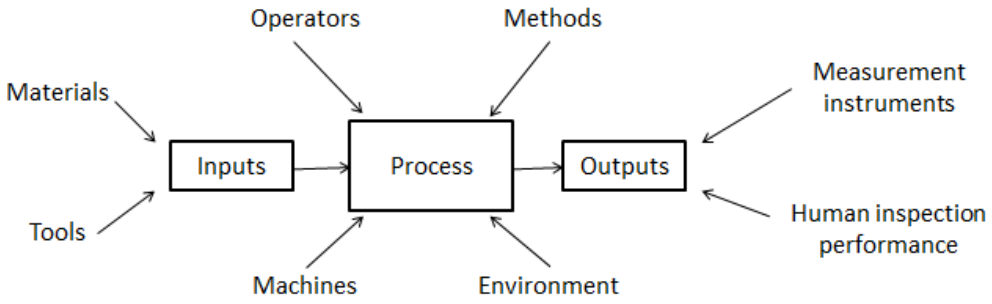

Figure 8. *Sources of variation in a process (Evans & Lindsay 2005)*

SPC is used to monitor the special causes of variation and act as an evidence for implementing an improvement. The process is said to be out of control when special causes are present. If common causes solely appear, the process is in statistical control. Control charts are a tool for improving both quality and productivity. In addition, it provides a way to demonstrate an organization's quality capability. (Evans & Lindsay 2005)

3.8.3 Control Charts

A run chart is a graph where data is plotted over time. A measurement is presented in vertical axis and time scale is in the horizontal axis. A control chart is a run chart with two added lines (control lines): the *Upper Control Limit* (UCL) and the *Lower Control Limit* (LCL). The control lines are chosen statistically to provide high probability. The purpose of control limits is to ease interpreting patterns in a run chart as well as make conclusions of the state of control. (Evans & Lindsay 2005)

The process, where the data is collected, is not stable when "sample values fall outside the control limits or if nonrandom patterns occur in the chart." In case of unstable process, corrective actions should be taken. Reacting fast to the results and executing corrective actions, the chance of manufacturing a nonconformance product is minimized. A control chart can, thus, seen as a problem-solving tool. (Evans & Lindsay 2005)

Variables data is data that can be measured on a continuous scale, such as height, length or width. Variables data are plotted in two charts, usually x-bar ($\bar{X}$) chart and a range (R) chart, when sample size is $n < 11$. The x-bar chart plots the sample means in between-sample variation, whereas range chart measures the within-sample variation. The x-chart is used to assess the centering and long-term variation in the process. Range chart assess short-term variation. (Sower 2011)

An x-bar chart construction begins with the collection of a series of samples, subgroups, from a process. A good sample consists of an observation size, n, of 3-10 (Evans &

Lindsay 2005). A sample mean ($\bar{x}$) is calculated by averaging the individual observations, i, in samples (subgroups) using equation 1. The grand mean (or x-double bar, $\bar{\bar{x}}$) is calculated by averaging at least 25 to 30 subgroups, k, by equation 2. The distribution for the x-chart is the normal distribution. (Sower 2011)

$$\bar{x} = \frac{\sum_{i=1}^{n} x_i}{n} \tag{1}$$

$$\bar{\bar{x}} = \frac{\sum_{i=1}^{k} \bar{x}_i}{k} \tag{2}$$

The *Center Line* (CL) is $\bar{\bar{x}}$ (x-double bar). The UCL is set at $\bar{\bar{x}} + 3\sigma_{\bar{x}}$ (+ 3 sigma) and calculated by equation 3. LCL is set at $\bar{\bar{x}} - 3\sigma_{\bar{x}}$ (–3 sigma) and is calculated by equation 4. The constant A_2 is found in Table 6. (Sower, 2011)

$$\text{UCL} = \bar{\bar{x}} + A_2\bar{R} \tag{3}$$

$$\text{LCL} = \bar{\bar{x}} - A_2\bar{R} \tag{4}$$

Table 6. *The constants for Control Charts (Sower 2011)*

n	A_2	A_3	c_4	B_3	B_4	D_3	D_4	d_2
2	1.880	2.659	0.7979	0	3.267	0	3.267	1.128
3	1.023	1.954	0.8862	0	2.568	0	2.575	1.693
4	0.729	1.628	0.9213	0	2.266	0	2.282	2.059
5	0.577	1.427	0.9400	0	2.089	0	2.115	2.326
6	0.483	1.287	0.9515	0.030	1.970	0	2.004	2.534
7	0.419	1.182	0.9594	0.118	1.882	0.076	1.924	2.704
8	0.373	1.099	0.9650	0.185	1.815	0.136	1.864	2.847
9	0.337	1.032	0.9693	0.239	1.761	0.184	1.816	2.970
10	0.308	0.975	0.9727	0.284	1.716	0.223	1.777	3.078
11	0.285	0.927	0.9754	0.321	1.679	0.256	1.744	3.173
12	0.266	0.886	0.9776	0.354	1.646	0.284	1.716	3.258
13	0.249	0.850	0.9794	0.382	1.618	0.308	1.692	3.336
14	0.235	0.817	0.9810	0.406	1.594	0.329	1.671	3.407
15	0.223	0.789	0.9823	0.428	1.572	0.348	1.652	3.472
16	0.212	0.763	0.9835	0.448	1.552	0.364	1.636	3.532
17	0.203	0.739	0.9845	0.466	1.534	0.379	1.621	3.588
18	0.194	0.718	0.9854	0.482	1.518	0.392	1.608	3.640
19	0.187	0.698	0.9862	0.497	1.503	0.404	1.596	3.689
20	0.180	0.680	0.9869	0.510	1.490	0.414	1.586	3.735
21	0.173	0.663	0.9876	0.523	1.477	0.425	1.575	3.778

One point falling outside the control limits indicates that the process may have shifted from $\bar{x}$ (out of control). A process may be out of control if 2 out of 3 points fall beyond the same ±2 sigma level or 4 out of 5 points fall beyond the same ±1 sigma level. Another ways to analyze whether the process is not stable, are pattern rules. A run of 7 or 8 points falling on one side (above or below) of the CL is an indicator that process average has shifted. Similarly, 7 or 8 points on a rising or falling trend indicated that the process is not in control. A situation where 9 out of 10 points fall within the ±1 sigma level (above or below the CL) is statistically out of control as well. (Kolarik 1999) Points close to the CL are an indicator that the control limits are too wide (or miscalculated) and needs re-calculation (Sower 2011).

In Figure 9 is an example of an x-bar chart from an extruder machine. The data collected in the starting point is seen on the left side. The CL was calculated and seen in longer dashed line. The LCL and UCL have been also calculated and they are seen in shorter dashed lines. The manufacturing extruder was upgraded and the data got from the extruder showed that 8 points fell under the CL. In this case the UCL, CL and LCL were re-calculated and the limits and data points are seen on the right. (Sower 2011)

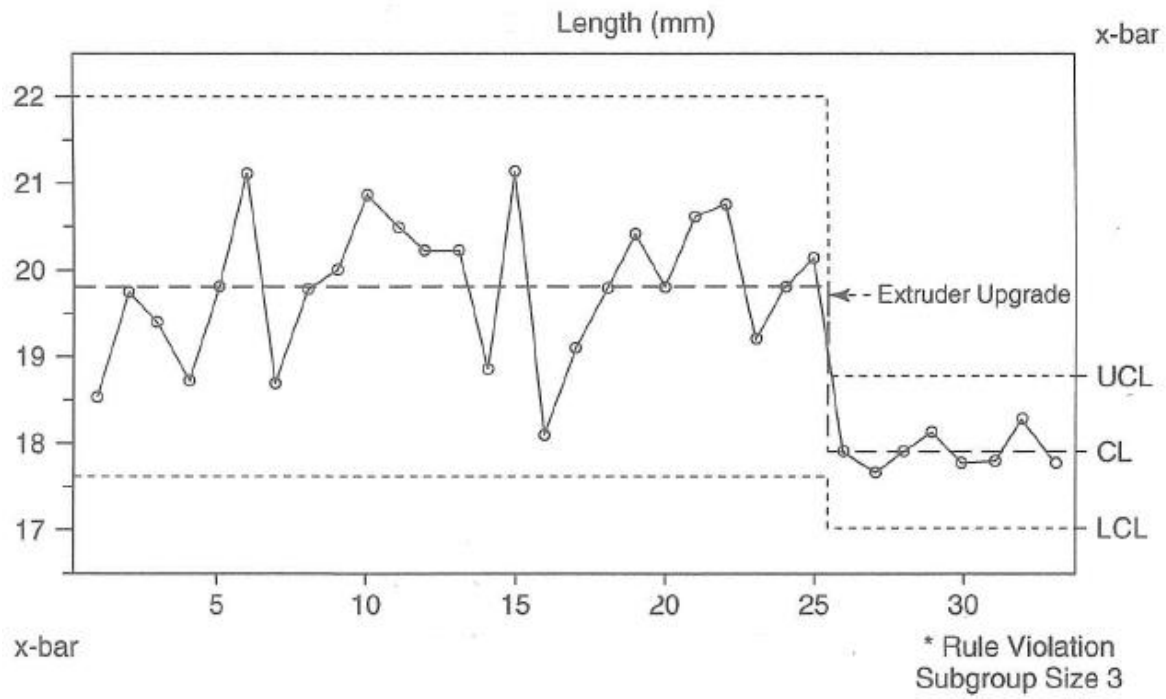

Figure 9. *X-bar Control Chart (Sower 2011)*

The centerline for R-chart is calculated in a similar way. For each of sample, the range is calculated by equation 5. The average range ($\overline{R}$) is calculated by equation 6. (Sower 2011)

$$\mathrm{R} = x_k(\text{largest}) - x_k(\text{smallest}) \tag{5}$$

$$\overline{R} = \frac{\sum_{i=1}^{k} R_i}{k} \tag{6}$$

The LCL and UCL for the R-chart are calculated by equations 7 and 8. The constants D_3 and D_4 are found in Table 6. (Sower 2011)

$$\mathrm{UCL} = \mathrm{D}_4\overline{R} \tag{7}$$

$$\mathrm{LCL} = \mathrm{D}_3\overline{R} \tag{8}$$

The range chart is first evaluated. In case of the range chart is in control, the x-chart can be evaluated. (Sower 2011)

4. RESULTS

4.1 General

The ISO 9001:2015 provides a basis for continuous improvement in organizations and IATF 16949 adds supplemental requirements. ISO 9001 certificate is important to Ahlstrom-Munksjö, Tampere Mill (AMTM) and therefore the organization decided to identify the gaps to fulfill ISO 9001:2015 and IATF 16949:2016 requirements.

However, the gaps identified are not presented in this public version by the request the organization where this study was done at.

4.2 Gap Analysis ISO 9001:2015

AMTM has ISO 9001:2008 certified QMS. Updated ISO 9001:2015 brings new requirements to the organization. In order to certify the QMS according to ISO 9001:2015 requirements, it is essential to recognize the gaps between the old, certified version and the new one. The ISO 9001:2015 gaps identified are not presented in this public version by the request the organization where this study was made at.

As a practical improvement, a new document was introduced to control and monitor the effectiveness of processes identified in AMTM. Also, relevant risks and opportunities were determined by the same template.

4.3 Gap Analysis IATF 16949:2016

AMTM has adopted some tools of the previous version of the automotive standard (ISO/TS 16949:2009), yet, the new release of the standard state requirements that have to be considered in order to get full compliance. The IATF 16949:2016 gaps identified are not presented in this public version by the request the organization where this study was done at.

As a practical approach, a study of a winder machine width capability was executed to introduce x- and R-charts as an example to meet the requirement of utilizing *Statistical Process Control* (SPC). Also process audit template and product audit templates were

introduced to the organization to strengthen proactivity and push improving inside the plant.

4.4 Limitations

Tampere Mill is a part of global Ahlstrom-Munksjö corporation. This research was done at Tampere Mill and does not include other plants or offices in Ahlstrom-Munksjö corporation. Certain activities, such as, customer satisfaction measurements (other than complaints, notifications or score cards by automotive customers) and sourcing are managed by global Ahlstrom-Munksjö group. Therefore these actions cannot be influenced at plant level.

Processes in the corporate level which have an effect on AMTM, but the research does not include or is not applicable to, are establishment of policies (code of conduct, anti-bribery policy), customer satisfaction measurement, sales office and global sourcing. However, the distinction between the global corporation and mill level is always not simple, because the actions are interrelated.

5. DISCUSSION

5.1 Review on the Research Results

The objective of the research was to conduct a gap analysis of the state of compliance to meet ISO 9001:2015 and IATF 16949:2016 requirements. The analysis identified gaps in the *Quality Management Systems* (QMS) of Ahlstrom-Munksjö, Tampere Mill to fulfill ISO 9001:2015 requirements. Certification is important for the organization and therefore, an action plan has been cascaded to gain compliance. The gap analysis of IATF 16949:2016 revealed additional gaps and some of them can be considered at the same time, when compliance plan of ISO 9001:2015 is addressed.

The reliability of the gap analysis is based on literature review on ISO 9001:2015 and IATF 16949:2016 standards. Repeatability of the review on the same versions of the standards is apparent, however, the interpretation of how to understand the standard requirements in practice, are necessarily not. The writer of the Thesis had no experience on the subject before starting this project, but training by external provider on ISO 9001:2015 requirements was found to be useful in the beginning of the project. Despite of the training, the understanding of the meaning of the requirements in practice in such a short time, was challenging. Thorough understanding of quality thinking and QMS comes during a longer time. And also recognizing that up keeping a QMS is a continuous project. For example, standards update regularly, environment and resources can change. In other words, implementing and maintaining a QMS is a never-ending project and therefore needs recognition of that.

Compliance to standard's requirements can be solved in different ways, depending, for instance, on the structure of the organization, size and complexity. Therefore, there is no one single solution to fulfill the gaps. Another important aspect is to gather the requirements linked together, before implementing actions toward each individual gap. Therefore, in the confidential version of the Thesis there are possible links to some other requirement presented, if there are any. The purpose is to help identifying stated requirements together in further use.

One part of the results in this Thesis was to implement actions towards conformity to meet ISO 9001:2015 and IATF 16949:2016 requirements. The usefulness of this part is to be seen in the future, for example, as the product audits and process audits are in use, and it is possible to gather information based on these actions. The templates can be possibly modified to fit better for their intended use, in case internal audit process provides such feedback. However, all actions focusing on proactivity provide reliability, in

terms that they offer information on possible faulty activities before the chance of producing nonconforming products is realized. The adequacy of implemented actions is to be seen in the certification audit of ISO 9001:2015 and possible certification audit of IATF 16949:2016 by the external auditor who evaluates the compliance of the implemented actions to the standard requirements.

5.2 Review on the Research Methods

The selected research methods – literature review, interviews and observations – were suitable for this research and all of them were needed to gain an understanding on the requirements in the QMS of AMTM. The main focus was on literature review in its different aspects. The research itself was based on ISO 9001:2015 and IATF 16949:2016 standard requirements. The given time period for this project was suitable to conduct the gap analysis. Yet, the practical part did not commence as effectively as the researcher would have hoped. This was mainly because lack of experience in understanding the scope of the project, lack of experience in the quality field as well as recognizing that it is natural that growing into certain position takes time.

The requirements in the standards were the foundation for the analyses. The literature review on academic research and quality related books gave also valuable information on the wide field of understanding quality as well as having practical touch on QMS implementation programs. A review on academic research offered practical experience on organizations utilizing QMS. In addition, some academic researchers interpreted some of the requirements into practical descriptions, yet recognizing that the interpretation is subjective and depends on the writer and his/her status in the field of quality. In this research, the review on academic research was a part of literature review, not part of the results. The academic research came from a reliable source since it was done from sources provided by the Tampere University of Technology (TUT). Also, consideration of the academic research reliability was done by evaluating the year of release before citing the article or research. Interviews – both formal and unstructured – and observations were a method for obtaining the information to gain the results. These subjective methods provided a way to interpret the standard requirements, however, the reliability might not be explicit.

5.3 Future Prospects based on the Results

Quality management affects the whole supply chain. Sometimes a motivator for the implementation of a quality standard is not internal but a customer requirement or at least a strong recommendation. Customers may have certified meta-standards, such as

IATF (former ISO/TS) 16949, and they want to stretch the requirements down in the supply chain to gain a better benefit in their own processes. Also, it helps communication when the same terms and tools are used.

As the gap analysis has been done in Ahlstrom-Munksjö, Tampere Mill to determine what things are missing from both ISO 9001:2015 and IATF 16949:2016 requirements, the next step is to develop an implementation plan that fits the needs and timelines of AMTM. However, to fulfill IATF requirements, the organization has to gain for full implementation of tools, such as, *Failure Mode and Effect Analysis* (FMEA), *Measurement System Analysis* (MSA), *Statistical Process Control* (SPC), *Product Part Approval Process* (PPAP) and *Advanced Product Approval process* (APQP).

Many responsibilities have been cascaded to top management in ISO 9001:2015 and IATF 16949:2016 requirements. However, the standards do not state that top management should solely fulfill the requirements. Instead, co-operation within the organization is essential and many of the responsibilities of top management can be delegated to sub processes. The main target is that by cascading top management responsibilities and further delegation, top management force processes to work for the same goal and engage many people to be involved.

QMS is not only aiming at products with high quality and performance but it is a system to manage operations in an organization. By managing operations successfully, the organization is able to produce high quality products. Internal motivation plays a huge role in an implementation process. In addition, motivation in all organizational levels is related to the success and pervasive utilization of QMS. In other words, motivation in implementing and adapting QMS cannot be achieved by a small group of people, yet it requires involvement and interest in the whole organization.

In the future, it is important to provide training for personnel of the ISO 9001:2015 and IATF 16949:2016 requirements, including statistical methods. In a longer period of time it would be useful to calculate the product performance targets and their upper and lower acceptance limits according to the latest data. All products have the same limits set once the products have been introduced to the production. In other words, some levels have been the same for several years and there has been no update after, for example, production line modernization. The best way to update the limits would be to utilize *Statistical Process Control* (SPC) methods, including x- and R -charts, introduced in Chapter 3.8.

In AMTM quality costs are not fully measured. Gathering the information would help to determine the ratio between how costs are divided between preventive, appraisal and correcting failures (internal and external). By changing the quality costs into financial language, it might be more effective to challenge personnel in all organizational levels to participate in the quality improvement process.

Meeting the ISO 9001:2015 and IATF 16949:2016 requirements is done by continuous improvement, step by step, because the quality improvement process is continuing. It is also a cultural change and a lot of new information of the standards is introduced during the implementation process. It has to be recognized that implementing takes time, because QMS – based on ISO 9001:2015 and IATF 16949:2016 requirements – effect on processes and is led by personnel. Human factors are not necessarily simple to manage. Therefore the organization should be proactive, as well, to recognize and sense areas where employees might need support or guidance. In the long run, it is beneficial to identify needs for support as soon as possible.

Auditors search for objective evidence, but it does not necessarily mean that things have to be solved in the exact same manners in each organization. In other words, the stated requirements can be solved in different ways, yet providing objective evidence on the conformity. Based on the implementation plan, a practical step is to update the existing system and execute internal audits on the QMS as a whole, as well as process and product audits. Ultimately the audit results, through proper corrective actions, will offer evidence on conformance to both ISO 9001:2015 and IATF 16949:2016 standards. Once the QMS is mature enough, a third-party audit can be executed to certify ISO 9001:2015 as a minimum, with the final objective at certifying IATF 16949:2016 in the future as well.

6. CONCLUSIONS

6.1 Results

The objective of the research was to find gaps in the *Quality Management System* (QMS) of Ahlstrom-Munksjö, Tampere Mill to meet the requirements stated in ISO 9001:2015 and IATF 16949:2016. Both of them are quality standards, and the latter is used in the automotive supply chain. An organization must be certified against ISO 9001:2015 requirements before it can certify IATF 16949:2016.

Gaps were found to meet the ISO 9001:2015 since the new release has pointed out certain things more vigorously. It emphasizes organizations to consider, for example, risk-based thinking more determinedly. Another important aspect is that quality is considered to be everybody's responsibility. Based on the gap analysis, an implementation plan is to be addressed to gain the compliance. However, it must be recognized that an implementation process takes time and needs careful planning.

Compliance to IATF 16949:2016 requirements also has to be addressed through a careful plan. Additional statistical tools, suggested by the standard, must be implemented. However, training is in key role again. Both quality standards, ISO 9001:2015 and IATF 16949:2016, must be understood by personnel in all organizational levels in order to gain the full benefit of them.

However, the standards offer a theoretical base of a QMS. In practice, compliance is not gained by following the standard clause by clause. An organization has to gather the information and build a solid QMS that fits the need and use of the specific organization. The QMS has to be flexible and personnel have to be alert to communicate relevant changes when they occur. That way, the QMS is kept up-to-date and as a tool for decision making.

6.2 Future Aspects

In case future research is conducted on the same organization, this Thesis can work as a baseline for full implementation process. However, the QMS is a wide concept and therefore the researcher suggests that effective and efficient results are able to gain if enough experience has been adapted in practice along with adequate trainings.

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